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Irish Society for Rheumatology

Spring Meeting 2019

12 April 2019
Radisson Blu Hotel
Stillorgan, Co. Dublin

Bristol-Myers Squibb janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson ucb

RoACTEMRA®
tocilizumab

Roche

10 YEARS TREATING PATIENTS

INDICATED FOR[1] RA | GCA | pJIA | sJIA

RA: Rheumatoid Arthritis; GCA: Giant Cell Arteritis; pJIA: Juvenile idiopathic polyarthritis; sJIA: Systemic juvenile idiopathic arthritis

ABRIDGED PRESCRIBING INFORMATION (API). For full prescribing information, refer to the Summary of Product Characteristics [SmPC]. RoActemra* (tocilizumab) 162mg solution for injection in pre-filled syringe (RoActemra SC PFS). RoActemra* (tocilizumab) 162mg solution for injection in pre-filled pen (RoActemra SC PFP). RoActemra* (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV). Indications: RoActemra SC PFS & PFP: In combination with methotrexate (MTX) for (i) the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX (ii) the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. RoActemra SC is also indicated for the treatment of Giant Cell Arteritis (GCA) in adults. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients ≥ 2 years of age, who responded inadequately to previous therapy with NSAIDs and systemic corticosteroids, (iv) juvenile idiopathic polyarthritis (pJIA) (rheumatoid factor positive or negative and extended oligoarthritis) in patients ≥ 2 years of age, who responded inadequately to previous therapy with MTX. RoActemra IV and RoActemra SC (in RA) can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. RoActemra IV/SC has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX for the treatment of adult RA patients. RoActemra is also indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, GCA, sJIA, pJIA or CRS and all patients should be given the Patient Alert Card. Assess suitability of patient for subcutaneous home use and instruct patient to inform HCP before administering the next dose if they experience symptoms of an allergic reaction. Patients should be instructed to seek immediate medical attention if they develop symptoms of serious allergic reactions. The first injection should be performed under the supervision of a qualified health care professional. Limited data available regarding switching patients from RoActemra IV to RoActemra SC. Patients switching from RoActemra IV to RoActemra SC should administer their first subcutaneous dose at the time of the next scheduled IV dose under the supervision of a qualified HCP. The first injection should be performed under the supervision of a qualified health care professional. A patient can self-inject RoActemra only if the physician determines that it is appropriate and the patient agrees to medical follow-up as necessary and has been trained in proper injection technique. **RA:** *RoActemra IV:* 8mg/kg body weight diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients >100kg, doses >800mg per infusion are not recommended. No data on doses above 1.2g. *RoActemra SC PFS & PFP:* Not intended for IV administration. RoActemra SC PFS is administered with a single-use PFS+NSD. RA - 162mg subcutaneous once every week, irrespective of weight. Patients may self-inject after training. Alternate injection site frequently (see SmPC for further details). Do not shake the syringe or pen. **GCA (RoActemra SC PFS & PFP only):** 162mg subcutaneous once every week in combination with a tapering course of glucocorticoids. RoActemra can be used alone following discontinuation of glucocorticoids. RoActemra monotherapy should not be used for the treatment of acute relapses as efficacy is not established in this setting. Based upon the chronic nature of GCA, treatment beyond 52 weeks should be guided by disease activity, physician discretion, and patient choice. Glucocorticoids should be given according to medical judgement and practice guidelines. **CRS (RoActemra IV):** in patients weighing ≥ 30kg, 8mg/kg diluted to a final volume of 100ml or, 12mg/kg diluted to final volume of 50ml for patients < 30kg, given by IV infusion over 1 hour. Can be given alone or in combination with corticosteroids. If no clinical improvement after the first dose, up to an additional 3 doses may be administered. The interval between consecutive doses should be at least 8 hours. Doses exceeding 800 mg per infusion are not recommended in CRS patients. Patients with severe or life-threatening CRS frequently have cytopenias or elevated ALT or AST due to the underlying malignancy, preceding lymphodepleting chemotherapy or the CRS. **sJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients ≥2 years, 8mg/kg diluted to final volume of 100ml for patients ≥ 30kg, or, 12mg/kg diluted to final volume of 50ml for patients < 30kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients <2 years of age - no data. Patients ≥2 years of age, 8mg/kg diluted to final volume of 100ml for patients ≥ 30 kg or 10 mg/kg diluted to final volume of 50ml for patients <30kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. A change in dose for sJIA/pJIA patients should only be based on a consistent change in the patient's body weight over time. *Dose adjustments:* For raised liver enzymes, modify concomitant DMARDs (RA) or immunomodulatory agents (GCA) if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). In patients not previously treated with RoActemra, initiation is not recommended in patients with an absolute neutrophil count (ANC) below 2 x 10^9/L. Refer to SmPC for information regarding missed subcutaneous doses. *Special Populations:* No data available for RoActemra SC in patients <18 years of age. Closely monitor renal function in patients with severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients >65 years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Special Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Do not initiate treatment in patients with active infections. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Vigilance for the timely detection of serious infection is recommended - signs and symptoms of acute inflammation may be lessened, due to suppression of the acute phase reaction. Consider effects of RoActemra on C-reactive protein (CRP), neutrophils and signs and symptoms of infection when evaluating a patient for a potential infection. Instruct patients and parents/guardians of sJIA and pJIA patients to contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Advise patients to seek medical attention if sign/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Promptly evaluate patients presenting with symptoms potentially indicative of complicated diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment even if they have received premedication with steroids and anti-histamines. Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction during treatment with RoActemra. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, immediately stop administration and permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. In clinical trials, transient or intermittent mild-moderate elevations of hepatic transaminases reported commonly with RoActemra treatment, without progression to hepatic injury. An increased frequency of these elevations was observed when potentially hepatotoxic drugs (e.g. MTX) were used in combination with RoActemra. When clinically indicated, consider other liver function tests including bilirubin. Not recommended in patients with baseline ALT or AST > 5 x ULN; caution in patients with ALT or AST > 1.5 x ULN (see SmPC for frequency of monitoring and dose modifications/interruptions). Decreases in neutrophil and platelet counts have occurred following treatment with RoActemra 8 mg/kg in combination with MTX. Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC < 0.5 x 10^9/L or platelet count < 50 x 10^3/µL. Do not initiate RoActemra treatment where ANC is below 2 x 10^9/L. Caution in patients with low platelet count; monitor neutrophils and platelets in RA, GCA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; assess every 4 to 8 weeks; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). RA patients have an increased risk for cardiovascular disorders - manage risk factors (e.g. hypertension, hyperlipidaemia) as part of usual standard of care. Not recommended for use with other biological agents. RoActemra (for IV use) contains 1.17 mmol (or 26.55 mg) sodium per maximum dose of 1200 mg – to be considered by patients on a controlled sodium diet. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients – RoActemra not studied in patients during an active MAS episode. Trade name and batch number should be clearly recorded in patient file to improve traceability of biological medicines. **Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or 2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions). **Fertility, Pregnancy & Lactation:** Women of childbearing potential (WCBP) must use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. An animal study showed increased risk of spontaneous abortion/embryo-foetal death at high dose. The potential risk for humans is unknown. RoActemra should not be used during pregnancy unless clearly necessary. It is unknown whether RoActemra is excreted in human breast milk. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Non-clinical data available suggests that RoActemra has no effect on fertility. Refer to SmPC. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV:** *RA:* The most commonly reported ADRs (occurring in ≥ 5% of patients treated with tocilizumab monotherapy or in combination with DMARDs) were upper respiratory tract infections, nasopharyngitis, headache, hypertension and increased ALT. The most serious ADRs were serious infections, complications of diverticulitis, and hypersensitivity reactions. ADRs occurring in RA trials: *Very Common (≥1/10):* upper respiratory tract infections, hypercholesterolaemia (including elevations collected as part of routing laboratory monitoring). *Common (≥1/100 - <1/10):* cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased (including elevations collected as part of routing laboratory monitoring), hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. *Uncommon (≥1/1000 - <1/100):* diverticulitis, stomatitis, gastric ulcer, hypertriglyceridaemia, nephrolithiasis, hypothyroidism. *sJIA:* ADRs were similar to those seen in RA patients. sJIA patients experienced a higher frequency of nasopharyngitis, decrease in neutrophil counts, hepatic transaminases increased, and diarrhoea. *Very Common (≥ 1/10):* upper respiratory tract infections, nasopharyngitis, decrease in neutrophil count. *Common (≥1/100 - <1/10):* diarrhoea, infusion related reactions, headache, platelet count decreased, cholesterol increased. *pJIA:* ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. *Very Common (≥ 1/10):* upper respiratory tract infections, nasopharyngitis, headache. *Common (≥1/100 - <1/10):* nausea, diarrhoea, infusion related reactions, hepatic transaminases increased, decrease in neutrophil count. *Uncommon (≥1/1000 - <1/100):* platelet count decreased, cholesterol increased. *CRS:* The safety of RoActemra in CRS has been evaluated in a retrospective analysis of data from clinical trials, where 51 patients were treated with intravenous RoActemra 8 mg/kg (12 mg/kg for patients less than 30 kg) with or without additional high-dose corticosteroids for severe or life-threatening CAR T-cell-induced CRS. A median of 1 dose of RoActemra (range, 1-4 doses) was administered. **RoActemra SC PFS & PFP:** RA - The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. GCA - The safety of subcutaneous RoActemra has been studied in one Phase III study (WA28119) with 251 GCA patients. The overall safety profile observed in the RoActemra treatment groups was consistent with the known safety profile of RoActemra. 6% of patients reported an ADR occurring at the site of a subcutaneous injection. Injection site reactions are reported as very common (≥ 1/10) with the use of the PFS and common (≥1/100 - <1/10) with the use of the PFP. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. *See SmPC section 4.8 for instructions on the reporting of suspected adverse reactions.* **Legal Category:** Subject to medical prescription which may not be renewed (A). **Presentations & Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/001); 200mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled pen (EU/1/08/492/009). **Marketing Authorisation Holder:** Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of API Preparation:** September 2018. *API (IE/RACTE/0816/0019(5)) based on the RoActemra 162 mg solution for injection in PFS and PFP SmPCs dated 12-Apr-2018 and RoActemra 20 mg/ml concentrate for solution for infusion SmPC dated 23-Aug-2018.* **References: 1.** RoACTEMRA Summary of Product Characteristics 15th January 2019. Available at www.medicines.ie. **Date of item:** February 2019. IE/RACTE/0219/0006

Welcome Message from the ISR President Dr Sinéad Harney

Dear Colleagues and Friends

Welcome to the Radisson Blu Hotel, Stillorgan, Co Dublin for the 2019 Irish Society of Rheumatology Spring meeting. I am very grateful to Prof Geraldine McCarthy and colleagues at the Mater Hospital Dublin for putting together a fabulous programme. The range and quality of topics and speakers lends itself to an interactive and interesting meeting. I would like to thank each of the speakers for taking the time to travel here to deliver their lectures. Thank you very much for giving of your time so freely.

As always a big thank you to Michael Dineen and Marie Caston and colleagues for their hard work in organising this meeting year on year.

Once again the Society is most grateful to our colleagues and friends from the Pharmaceutical industry, who are here in great numbers, for their continued financial support.

Lastly, I would like to encourage all my female colleagues to join Grainne O Leary and I in running the Dublin mini marathon to raise awareness about arthritis in this country and to advocate for improved services for patients.

Enjoy the meeting

Dr Sinéad Harney
ISR President

ISR Board Back Row: Dr Bryan Whelan, Prof Suzanne Donnelly, Dr Adrian Pendleton, Prof Ursula Fearon, Mr Michael Dineen, Dr John Ryan, Dr Shawn Chavrimootoo: Front Row Dr Aine Gorman, Dr Sinead Harney, Dr Clare Matthews and Dr Bernadette Lynch

MADE IN IRELAND

RAPID AND SUSTAINED EFFICACY[2-8]

A MARK OF XELJANZ▼

WHEN csDMARDs ARE NOT ENOUGH: PRESCRIBE XELJANZ [1,9,10]

XELJANZ®
(tofacitinib citrate)

SMALL PILL. BIG IMPACT.[2-4,11]

XELJANZ® ▼(tofacitinib) Prescribing Information:

Please refer to the Summary of Product Characteristics (SmPC) before prescribing XELJANZ 5 mg or 10 mg film-coated tablets. **Presentation:** Film-coated tablet containing tofacitinib citrate, equivalent to 5 mg or 10 mg tofacitinib. **Indications:** In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. Can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. In combination with MTX for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease modifying antirheumatic drug (DMARD) therapy. For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. **Dosage:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Tofacitinib is given with or without food. ***RA and PsA:*** The recommended dose is 5 mg administered orally twice daily. ***UC:*** The recommended dose is 10 mg given orally twice daily for induction for 8 weeks and 5 mg given twice daily for maintenance. For patients who do not achieve adequate therapeutic benefit by week 8, the induction dose of 10 mg twice daily can be extended for an additional 8 weeks (16 weeks total), followed by 5 mg twice daily for maintenance. Tofacitinib induction therapy should be discontinued in any patient who shows no evidence of therapeutic benefit by week 16. For some patients, such as those who have failed prior tumour necrosis factor (TNF) antagonist therapy, consideration should be given to continuation of the 10 mg twice daily dose for maintenance in order to maintain therapeutic benefit (see SmPC section 5.1). Patients who experience a decrease in response on tofacitinib 5 mg twice daily maintenance therapy may benefit from an increase to tofacitinib 10 mg administered twice daily. It is recommended not to initiate dosing in patients with an absolute lymphocyte count (ALC) less than 0.75 x 10^9/l, an absolute neutrophil count (ANC) less than 1x10^9 /l or in patients with haemoglobin less than 9 g/dL. ***Renal impairment:*** No dose adjustment is required in patients with mild or moderate renal impairment. Patients with severe renal impairment the dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal renal function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal renal function is 10 mg twice daily. Patients with severe renal impairment should remain on a reduced dose even after haemodialysis. ***Hepatic impairment:*** No dose adjustment is required in patients with mild hepatic impairment. Patients with moderate hepatic impairment dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal hepatic function is 5 mg twice daily.Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal hepatic function is 10 mg twice daily. Tofacitinib should not be used in patients with severe hepatic impairment. ***Elderly:*** No dose adjustment is required in patients aged 65 years and older. Use with caution as increase risk and severity of adverse events. ***Drug–drug Interactions:*** XELJANZ dose should be reduced to 5 mg once daily in patients receiving potent inhibitors of cytochrome (CYP) P450 3A4 (e.g., ketoconazole). XELJANZ dosage should be reduced to 5 mg once daily in patients receiving one or more concomitant medicinal products that result in both moderate inhibition of CYP3A4 as well as potent inhibition of CYP2C19 (e.g., fluconazole) Coadministration of XELJANZ with potent CYP inducers (e.g., rifampicin) may result in a loss of or reduced clinical response. Coadministration of potent inducers of CYP3A4 with XELJANZ is not recommended. **Contraindications:** Hypersensitivity to any of the ingredients, active tuberculosis (TB), serious infections such as sepsis, or opportunistic infections, severe hepatic impairment, pregnancy and lactation. **Warnings and Precautions:** Tofacitinib should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Patients treated with tofacitinib should be given a patient alert card. There was a higher incidence of adverse events for the combination of tofacitinib with MTX versus tofacitinib as monotherapy in RA clinical studies. Tofacitinib should be avoided in combination with biologics and potent immunosuppressants such as azathioprine, 6-mercaptopurine, ciclosporine and tacrolimus. ***Infections:*** Serious and sometimes fatal infections have been reported in patients administered tofacitinib. Rheumatoid arthritis patients taking corticosteroids may be predisposed to infection. Patients should be closely monitored for infections, with prompt diagnosis and treatment. Treatment should be interrupted if a serious infection develops. Use carefully in elderly or patients predisposed to, or with a history of infection (e.g. diabetes). ***Tuberculosis:*** Patients should be evaluated for both active and latent TB prior to being treated with tofacitinib, patients who test positive for latent TB should be treated with standard antimycobacterial therapy before administering tofacitinib. ***Viral Reactivation:*** In clinical studies viral reactivation and cases of herpes zoster have been observed. Screening for viral hepatitis should be performed in accordance with clinical guidelines prior to starting therapy with tofacitinib. The impact on chronic viral hepatitis is not known. ***Vaccinations:*** Prior to initiating tofacitinib, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Live vaccines should not be given concurrently with tofacitinib. ***Malignancy:*** Lymphomas and other malignancies have been observed in patients treated with tofacitinib. Patients with highly active disease may be at higher risk than the general population. The effect of tofacitinib on the development and course of malignancies is not known. NMSCs have been reported, the risk of NMSC may be higher in patients treated with tofacitinib 10 mg twice daily than in patients treated with 5 mg twice daily. Periodic skin examination is recommended in patients at increased risk. ***Interstitial lung disease:*** Caution is recommended in patients with a history of chronic lung disease as they may be more prone to infection. Asian patients are known to be at higher risk of ILD caution should be exercised with these patients. ***Gastrointestinal perforations:*** Tofacitinib should be used with caution in patients who may be at increased risk e.g. diverticulitis or concomitant use of corticosteroids or NSAIDs. ***Cardiovascular risk:*** Risk factors should be managed as part of usual standard of care. ***Hypersensitivity:*** Cases of drug hypersensitivity associated with tofacitinib administration have been reported. Allergic reactions included angioedema and urticaria; serious reactions have occurred. If any serious allergic or anaphylactic reaction occurs, tofacitinib should be discontinued immediately . ***Laboratory Parameters:*** Increased incidence of lymphopenia and neutropenia have been reported and decreases in haemoglobin and should be monitored in accordance with the SmPC. Monitor ANC and haemoglobin at baseline, 4-8 weeks and 3 monthly, ALC at baseline and 3 monthly. Tofacitinib has been associated with increases in lipid parameters maximal effects are observed at 6 weeks. Monitoring should be performed 8 weeks after initiation and managed according to hyperlipidemia guidelines. Increases in liver enzymes greater than 3x ULN were uncommonly reported, use caution when initiating with potential hepatotoxic medicinal products. **Pregnancy & Lactation:** Use of tofacitinib during pregnancy and breast-feeding is contraindicated. **Side Effects:** The most common serious adverse reactions were serious infections; pneumonia, cellulitis, herpes zoster, UTIs, diverticulitis, appendicitis and opportunistic infections. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials were headache, upper respiratory tract infections, nasopharyngitis, diarrhoea, nausea and hypertension. The most commonly reported adverse reactions in patients receiving tofacitinib 10 mg twice daily in the induction studies were headache, nasopharyngitis, nausea, and arthralgia. Commonly reported adverse reactions (≥1/100 to <1/10), were pneumonia, influenza, herpes zoster, urinary tract infection, sinusitis, bronchitis, nasopharyngitis, pharyngitis, anaemia, headache, hypertension, cough, abdominal pain, vomiting, diarrhoea, nausea, gastritis, dyspepsia, rash, arthralgia, pyrexia, oedema peripheral, fatigue, blood creatine phosphokinase increased. Refer to section 4.8 of the SmPC for further information on side effects, including description of selected adverse reactions. **Legal Category:** S1B. **Marketing Authorisation Number:** EU/1/16/1178/003 – 5 mg (56 film-coated tablets); EU/1/16/1178/007 – 10 mg (56 film-coated tablets). **Marketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. ***For queries regarding product availability please contact:*** Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

Last revised: 11/2018.

Ref: XJ 6_0.

References:
1. XELJANZ Summary of Product Characteristics. **2.** van Vollenhoven RF *et al. N Engl J Med* 2012; 367: 508–519. **3.** van der Heijde D *et al. Arthritis Rheum* 2013; 65: 559–570. **4.** Fleischmann R *et al. N Engl J Med* 2012; 367: 495–507. **5.** Strand V *et al. Ann Rheum Dis* 2017; 76: 1335. **6.** Wollenhaupt J *et al.* Poster presented at: American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting; November 3–8, 2017; San Diego, CA, USA. **7.** Mease P, et al. N Engl J Med 2017; 377: 1537–1550. **8.** Gladman D, et al. N Engl J Med 2017; 377: 1525–1536 **9.** Smolen JS *et al. Ann Rheum Dis* 2017 Mar 6. [Epub ahead of print]. **10**. Singh JA *et al. Arthritis Rheumatol* 2016; 68: 1–26. **11.** Burmester GR *et al. Lancet* 2013; 381(9865): 451–460.

PP-XEL-IRL-0381 | Date of preparation: January 2019

ISR Spring Meeting

Friday, 12 April 2019 – Radisson Blu, Stillorgan, Co Dublin

Programme

08.30-09.30	Registration
09.00-09.55	**CAG Meeting for Consultant Members** Lead: **Prof David Kane** Chair: **Dr Sinead Harney**
09.55-10.00	**Welcome Address by ISR President:** **Dr Sinead Harney**
10.00-10.45	**Prof Gary Macfarlane** Clinical Chair in Epidemiology, Dean of Research & Knowledge Exchange (Life Sciences and Medicine) University of Aberdeen, UK Topic: ***"Why do people with chronic pain die prematurely?"***
10.45-11.30	**Prof Catherine Nelson Piercy** Consultant Obstetric Physician Guys and St Thomas Foundation Trust and Imperial College Healthcare Trust Topic: ***"Pregnancy in Rheumatology Patients"***
11.30-12.00	Coffee, Poster Viewing and Visit the Industry
12.00-12.45	**Prof Raashid Luqmani** Professor of Rheumatology, University of Oxford, UK Topic: ***"An update on the vasculitides"***
12.45-14.15	Lunch, Poster Viewing and Visit the Industry
14.15-15.00	**Dr Austin O'Carroll** Mountjoy St. Family Practice, Topic: ***"Managing Health in time of chaos"***
15.00-16.00	**Prof Andrea Kalus** Associate Professor Dermatology, University of Washington, Seattle Topic: ***"Dermatology for Rheumatologists"***

FOR RA PATIENTS WITH POOR PROGNOSTIC FACTORS, **TIME IS OF THE ESSENCE**[1–4]

RA patients with high disease activity, including **ACPA/RF seropositive patients**, are likely to have significantly worse and faster disease course vs seronegative, and **must be identified as soon as possible**[1–4]

Early treatment with **ORENCIA® prevents irreversible radiographic progression**[5]

ORENCIA® is even more **effective in ACPA seropositive** patients than seronegative patients[6]

Your at-risk patients may **stay the course with ORENCIA®** due to low rates of drug-related discontinuations[5,7]

ORENCIA, in combination with methotrexate, is indicated for:

- **The treatment of moderate to severe active RA in adult patients who responded inadequately to previous therapy with one or more DMARDs including MTX or a TNF-alpha inhibitor**
- **The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with MTX**

ORENCIA® (abatacept)
CLICKJECT®
PRE-FILLED PEN

A convenient option for patients who choose self-injection[7]

Don't wait until it's too late; RA patients with poor prognosis require your attention to prevent their disease from progressing[1–4]

Bristol-Myers Squibb

March 2019 427UK1900255-01

ORENCIA® (abatacept)
PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing and for full information on the medicinal product

PRESENTATION: 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial; each ml contains 25 mg of abatacept, after reconstitution. 125 mg pre-filled syringe and ClickJect pre-filled pen, for SC injection; each pre-filled syringe and pen contains 125 mg of abatacept in 1 ml.
INDICATION: Rheumatoid arthritis (RA) (IV infusion, SC pre-filled syringe and pen):
Orencia, in combination with methotrexate, is indicated for:
- The treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate or a tumour necrosis factor (TNF)-alpha inhibitor.
- The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.

A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate, see SmPC. ***Psoriatic Arthritis ((PsA) IV infusion, SC pre-filled syringe and pen)***: Orencia alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required. ***Polyarticular Juvenile Idiopathic Arthritis (pJIA) {IV infusion only}***: Orencia in combination with methotrexate is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. **DOSAGE:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA or PsA. Orencia 250 mg powder for concentrate for solution for IV infusion *Adults and elderly*: Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≤ 60 kg to ≥ 100 kg: 750 mg (3 vials). Patients weighing > 100kg: 1000 mg (4 vials). *Treatment of pJIA*: Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg. Paediatric patients weighing 75 kg or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orencia IV should be given at 2 and 4 weeks, then every 4 weeks thereafter. *Children:* Use in children below 6 years of age is not recommended. Orencia 125 mg solution for injection (SC *pre-filled syringe and pen*) *Adults and elderly*: Orencia SC may be initiated with or ithout an IV loading dose. Orencia SC should be administered weekly at a dose of 125 mg by subcutaneous injection regardless of weight. If a single IV infusion is given to initiate treatment (IV loading dose before SC administration), the first 125 mg abatacept SC should be administered within a day of the IV infusion, followed by the weekly 125 mg abatacept SC injections. Patients transitioning from Orencia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. *Children:* The safety and efficacy of Orencia SC in children below 18 years of age have not been established. The continuation of treatment with abatacept should be re-assessed if patients do not respond within 6 months. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections. **WARNINGS AND PRECAUTIONS:** *Allergic Reactions*: Caution in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions can occur after the first infusion and can be life threatening. Orencia IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactic reaction. *Infections:* Caution should be exercised when considering use in patients with a history of frequent infections, or underlying conditions which may predispose to infection. Treatment with Orencia should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orencia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orencia. Co-administration of Orencia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orencia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. *Malignancies:* The potential role of Orencia in the development of malignancies is unknown. However periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. *Elderly:* Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. *Autoimmune processes:* Theoretical risk of deterioration in autoimmune disease. *Immunisation:* Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orencia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orencia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orencia in combination with sulfasalazine, hydroxychloroquine or leflunomide. **PREGNANCY AND LACTATION:** Abatacept may cross the placenta into the serum of infants born to women treated with abatacept during pregnancy. Consequently, these infants may be at increased risk of infection. Administration of live vaccines to infants exposed to abatacept in utero is not recommended for 14 weeks following the mother's last exposure to abatacept during pregnancy. Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In clinical trials and post-marketing experience, the following adverse drug reactions were reported. *Very Common (≥ 1/10):* upper respiratory tract infection including tracheitis, nasopharyngitis, sinusitis. *Common (≥ 1/100 to < 1/10)*: Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), pneumonia, influenza, headache, dizziness, hypertension blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), fatigue, asthenia, local injection site reactions*, systemic injection reactions* (e.g. pruritus, throat tightness, dyspnea) *Uncommon (≥ 1/1,000 to < 1/100)*: Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, rhinitis, ear infection, basal cell carcinoma, skin papilloma, thrombocytopenia, leukopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, paraesthesia, conjunctivitis, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, blood pressure decreased, hot flush, flushing, vasculitis, chronic obstructive pulmonary disease exacerbated, bronchospasm, wheezing, dyspnea, throat tightness, gastritis, increased tendency to bruise, dry skin, alopecia, pruritus, urticaria, psoriasis, acne, erythema, hyperhidosis, arthralgia, pain in extremity, amenorrhea, menorrhagia, influenza like illness, weight increased. *Rare (≥ 1/10,000 to < 1/1,000)*: Tuberculosis, bacteraemia, gastrointestinal infection, pelvic inflammatory disease, lymphoma, lung neoplasm malignant, squamous cell carcinoma. *Orencia SC, see SmPC for information on other undesirable effects. **LEGAL CATEGORY:** POM **MARKETING AUTHORISATION NUMBER AND BASIC NHS PRICE [*UK only*]:** Orencia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack: £302.40 Orencia 125 mg solution for Injection (pre-filled syringe)-EU/1/07/389/008 and ClickJect pre-filled pen - EU/1/07/389/011, 4 pre-filled syringes with needle guard: £1209.60 4 pre-filled pens: £1209.60 **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK. Tel: 0800-731-1736 **LOCAL REPRESENTATIVE IN UK:** Bristol-Myers Squibb Pharmaceuticals Limited, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK. Tel: 0800-731-1736 **LOCAL REPRESENTATIVE IN IRELAND:** Bristol-Myers Squibb Pharmaceuticals uc, Plaza 254, Blanchardstown Corporate Park 2, Ballycoolin, Dublin, D15 T867, Ireland. Tel: 01 483 3625 **DATE OF LAST REVISION:** July 2017
ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Adverse events should be reported. Reporting forms and information can be found at: UK - www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store; Ireland - Freepost HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie. Adverse events should also be reported to Bristol-Myers Squibb via medical.information @bms.com or 0800 731 1736 (UK); 1 800 749 749 (Ireland).

REFERENCES: 1. Lamerato L *et al. J Med Econ* 2018;21(3):231–40. **2.** Sokolove J *et al. Arthritis Rheumatol* 2014;66(4):813–21. **3.** van der Helm-van Mil AHM *et al. Arthritis Res Ther* 2005;7(5):R949–R958. **4.** National Institute for Health and Care Excellence. Rheumatoid arthritis in adults: management. NICE guideline. Published: 11 July 2018. Available at nice.org.uk/guidance/ng100 (last accessed: February 2019). **5.** Schiff M *et al. Ann Rheum Dis* 2014;73(1):86–94. **6.** Sokolove J *et al. Ann Rheum Dis* 2016;75(4):709–14. **7.** ORENCIA® SmPC. Available at www.medicines.org.uk/emc (last accessed: February 2019).

ABBREVIATIONS: ACPA, anti-citrullinated protein antibody; DMARD, disease modifying anti-rheumatic drug; MTX, methotrexate; RA, rheumatoid arthritis; RF, rheumatoid factor; TNF, tumour necrosis factor.

March 2019
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Biographical Sketches

Speakers

Prof Gary Macfarlane
Clinical Chair in Epidemiology,
Dean of Research & Knowledge Exchange (Life Sciences and Medicine)
University of Aberdeen, UK

Gary Macfarlane is Dean of Research and Knowledge Exchange (Life Sciences and Medicine) at The University of Aberdeen. He has also been Chair in Epidemiology since 2005. He is an Honorary Consultant in Public Health with NHS Grampian. He trained in Statistics/Computing Science and then Medicine at The University of Glasgow before undertaking his PhD on the Epidemiology of Oral Cancer at The University of Bristol. He worked at the Division of Epidemiology and Biostatistics at the European Institute of Oncology in Milan 1991-1995 before leading a programme of chronic pain research at the Arthritis Research UK Epidemiology Unit at the University of Manchester, where he was appointed as chair in 1999. He currently leads the Epidemiology group at the University of Aberdeen which undertakes work on Rheumatic and Musculoskeletal Diseases (RMD). The RMD programme focuses on: mechanistic research, clinical trials and health services research with a clinical focus on musculoskeletal pain and fatigue (including fibromyalgia), spondyloarthritis and rare diseases (vasculitis). The programme runs the British Society of Rheumatology (BSR) Biologics Registers in Ankylosing Spondylitis (BSRBR-AS) and Psoriatic Arthritis (BSR-PsA). He is a senior investigator within the Arthritis Research UK/ Medical Research Council Centre for Musculoskeletal Health and Work (with University of Southampton). Professor Macfarlane is a Chartered Statistician of the Royal Statistical Society as well as a Fellow of the Faculty of Public Health Medicine.

Prof Catherine Nelson Piercy
Consultant Obstetric Physician Guys and St Thomas Foundation Trust and Imperial College Healthcare Trust

Catherine Nelson-Piercy is a Consultant Obstetric Physician at Guy's and St. Thomas' Hospitals Trust and Queen Charlotte's and Chelsea Hospital in London. In 2010 she was awarded the title of Professor of Obstetric Medicine at King's College London. Her undergraduate studies were at King's College, Cambridge University and St Bartholomew's Hospital. She trained as a physician, and was taught Obstetric Medicine by Professor Michael de Swiet.
Professor Nelson-Piercy is past President of the International Society of Obstetric Medicine (ISOM). She is founding co-editor in chief of the journal 'Obstetric Medicine: the medicine of pregnancy.'
Professor Nelson-Piercy has been involved in the development of several evidence-based National Guidelines notably for "Contraception in Women with Heart Disease", BTS / SIGN "Asthma in Pregnancy" and RCOG Green top guidelines on "Reducing the risk of thromboembolism during pregnancy, birth & the puerperium" and 'Management of nausea vomiting of pregnancy and hyperemesis gravidarum". She has over 200 publications and has edited five books and written the successful Handbook of Obstetric Medicine, now in its fifth edition. She is also one of the central physician assessors for the UK Confidential maternal deaths enquiry.

Prof Andrea Kalus
Associate Professor Dermatology,
University of Washington, Seattle

Andrea Kalus trained in both internal medicine and dermatology at the University of Washington. Following her training she joined the faculty in Dermatology and is the Director of the Combined Dermatology Rheumatology Clinic at the University of Washington. In this practice setting she works alongside Rheumatology colleagues and fellows in training. She regularly teaches students and residents in clinical settings and has a role in the medical school as a mentor and teacher within a 4 year integrated curriculum of clinical skills and professionalism. For the last 10 years Andrea has co-directed a visual skills course for medical students and conducted workshops for faculty on visual observation. She has a special interest in the application of the humanities disciplines to the practice of medicine.

Prof Raashid Luqmani
Professor of Rheumatology, University of Oxford, UK

Professor of Rheumatology at the University of Oxford (since 2011) and a Consultant Rheumatologist in Oxford (since 2005). Prior to this he has been a consultant rheumatologist in Edinburgh from 1994-2005. He trained as an undergraduate in Nottingham and has an interest in the systemic vasculitides for a number of years. Raashid developed the Birmingham Vasculitis Assessment Score, and has taken part in several clinical studies of vasculitis, including the evaluation of the role of ultrasound in the diagnosis of giant cell arteritis. He recently led the development of new classification criteria in vasculitis.

Dr Austin O'Carroll
Mountjoy St. Family Practice

Dr Austin O Carroll is a GP in Inner City Dublin. He has a deep interest in Health Inequalities. He started eight specialised primary care services for homeless people and founded Safetynet, the umbrella organisation for primary care services for health services for homeless people which is provided in 18 hostels and food halls/drop ins Dublin, Limerick and Cork. He founded a mobile outreach clinic for rough sleepers. Safetynet also provides services to the Roma community; methadone services to homeless people; and services to migrants. He also founded the North Dublin City GP Training programme, the first GP training programme internationally that specifically trains GP's to work in areas of deprivation and

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References:
1. HUMIRA Summary of Product Characteristics, available on www.medicines.ie. **2.** Commission implementing directive 2012/52/EU of 20 December 2012.
3. Medicinal Products (Prescription and Control of Supply) (Ammendment) (No.2) Regulations 2014. SI No. 504 2014.

* Brand name should be used if the prescribed product is a biologic medicine
Further information is available upon request from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, D24 XN32
Full prescribing information is available at www.medicines.ie.
Legal Category: POM
Date of preparation: March 2019; IE-HUM-190005

with marginalised groups. He co-founded the Partnership for Health Equity between the HSE Social Inclusion, NDCGP, ICGP and University of Limerick. He co-founded GMQ GP services for homeless people. He co-founded Curam, a new social enterprise that is setting up New GP practices in areas of deprivation. He was a founding member of D-Doc. He sails on the Irish Paralympic Sailing Team. Austin has received the Time & Tide Award for his work with migrants; the Fiona Bradley Award for providing primary care to marginalised groups; and the Healthcare professional of the Year Award 2015.

ISR Board members

Dr Sinéad Harney
President

Dr Sinéad Harney graduated from UCG in 1994 and did her specialist training in Rheumatology and General Medicine in Dublin. She completed her training in Oxford in 2005 and was awarded a DPhil by thesis titled "Major Histocompatibility Genetics of Rheumatoid Arthritis". She was appointed to a Consultant Rheumatologist post in Cork University Hospital in 2005 and has worked there since. She completed a Masters in Sports and Exercise Medicine in UCC in 2007. Her research interests include – Genetics of inflammatory arthritis and occult cardiovascular disease in Rheumatoid Arthritis and she has over 90 publications. She is currently the treasurer of the Irish Society of Rheumatology and a board member of the TUE committee of the Irish Sports Council.

Dr Clare Matthews
Honorary Secretary

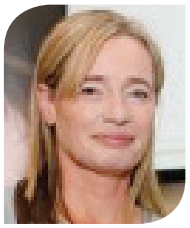
Consultant Rheumatologist, Ulster Hospital, Belfast Dr Clare Matthews graduated from Queens University Belfast in 1994. She completed registrar training with CCT in Rheumatology and general medicine in 2007. She completed an MD "Clinical, genetic and immunohistochemical findings of early inflammatory arthritis" from The Queen's University, Belfast in 2004. She trained in Belfast with a period of training in St Vincent's University Hospital Dublin through her research interest in synovial disease. Dr Matthews was first appointed as a consultant in Belfast City Hospital and moved to her current post in The South Eastern Trust in 2009.

Dr John Ryan
Honorary Treasurer

Dr John Ryan is a graduate of the Royal College of Surgeons in Ireland, he completed his higher medical training in rheumatology and general internal medicine in Ireland. He undertook a fellowship at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in Bethesda, Maryland. During this time he undertook translational research into disordered innate immunity manifesting as recurrent fever syndromes. He joined Dr Sinead Harney in the Rheumatology service at Cork University Hospital in 2010. The Rheumatology department has since expanded to include Dr Grainne Murphy. In July 2017 he took up the post of National Specialty Director for Rheumatology.

Dr Shawn Chavrimootoo
Shawn Chavrimootoo is a Consultant Rheumatologist at Our Lady's Hospital, Navan, Co. Meath. He graduated in Medicine from RCSI, Dublin in 2002 and developed an interest in Rheumatology during his Senior House Officer years in Connolly Hospital, Blanchardstown. Following this, he completed higher specialist training in Cork University Hospital, Kerry General Hospital, Connolly Hospital and St Vincent's University Hospital in Dublin. He was appointed to his Consultant Rheumatologist post in 2013 when he joined Dr Ramakrishnan at Our Lady's Hospital, Navan, from where they currently provide a regional Rheumatology service for the North East of Ireland. His clinical interests include osteoporosis as well as gout, inflammatory arthritis, spondyloarthritis, connective tissue disease and vasculitis.

Professor Suzanne Donnelly
Associate Professor Suzanne Donnelly is a consultant rheumatologist at the Mater Misericordiae University Hospital Dublin & Associate Dean (Education) in UCD School of Medicine. She is a graduate of Trinity College Dublin and trained in Dublin and Oxford before being appointed consultant rheumatologist at St. George's Hospital and Medical School, London in 2002. Her clinical interests include systemic autoimmune disease, Systemic Lupus Erythematosus and pregnancy in the rheumatic diseases . Suzanne has held academic posts in medical education since 1996 including in Trinity College Dublin; the University of Oxford and in London. She joined UCD as Director of Clinical Education in 2008, and was appointed Associate Dean, UCD School of Medicine in 2017. In partnership with Arthritis Ireland , she initated a patient educator programme to enhance medical students' education in rheumatological disease. The programme has enabled over 2000 medical students to meet patients with arthritis first hand. Suzanne is rheumatology author for the medical textbook Medicine at A Glance and a contributing author to The Rheumatology Handbook. She was ISR nominee to the board of Arthritis Ireland (2008-13), a board member of Raynauds and Scleroderma Ireland (2007-10) and medical patron of Lupus Group Ireland.



Professor Ursula Fearon
Professor Ursula Fearon is head of Molecular Rheumatology, School of Medicine, Trinity Biomedical Sciences Institute, Trinity College Dublin. Professor Fearon's research is a bench-to-beside translational approach, focusing on understanding the underlying mechanisms that drive disease pathogenesis; her team specifically examine components of joint inflammation at a cellular and molecular level to dissect out the signalling and gene pathways that are involved in

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ABRIDGED PRODUCT INFORMATION Refer to Summary of Product Characteristics before prescribing **PRESENTATION** Simponi 50 mg solution for injection in pre filled pen Simponi 50 mg solution for injection in pre filled syringe Simponi 100 mg solution for injection in pre filled pen **INDICATIONS** *Rheumatoid Arthritis (RA):* Simponi, in combination with methotrexate (MTX), is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA):* Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS):* Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* Simponi is indicated for the treatment of severe, active *nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. Ulcerative colitis (UC):* Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. *Polyarticular juvenile idiopathic arthritis (pJIA):* Simponi 50mg in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX. **DOSAGE AND ADMINISTRATION** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA, UC or pJIA. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. *RA:* Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. *PsA:* Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. *AS and nr-Axial SpA:* Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. *UC: Patients weighing < 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2. Patients who have an adequate response should receive 50 mg at week 6 and every 4 weeks thereafter. Patients who have an inadequate response may benefit from continuing with 100 mg at week 6 and every 4 weeks thereafter. *Patients weighing ≥ 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12 14 weeks of treatment (after 4 doses). *pJIA:* Simponi 50 mg administered once a month, on the same date each month, for children with a body weight of at least 40 kg. Clinical response is usually achieved within 12 to 14 weeks of treatment (after 3 4 doses). *Missed dose:* If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. *Older patients (≥ 65 years):* no dose adjustment required. *Paediatric patients (<18 years):* For indications other than pJIA, Simponi is not recommended. *Patients with renal and hepatic impairment:* Simponi is not recommended. **CONTRAINDICATIONS** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS AND WARNINGS** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Reminder Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. *Hepatitis B (HBV) reactivation:* Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi *Malignancies and lymphoproliferative disorders:* Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6 mercaptopurine (6–MP). The potential risk with the combination of AZA or 6 MP and Simponi should be carefully considered. A risk for the development for HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma and Merkel cell carcinoma (all TNF-blocking agents including Simponi) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. *Heart Failure:* Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. *Neurological events:* Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. *Surgery:* Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. *Autoimmune processes:* If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. *Haematological reactions:* There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anaemia, and thrombocytopaenia in patients receiving TNF-blockers, including Simponi. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. *Vaccinations/therapeutic infectious agents:* It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. *Allergic reactions:* If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. *Special populations: Older patients (≥ 65 years):* Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. *Paediatric patients (<18 years): Vaccinations:* it is recommended that prior to initiating Simponi therapy, paediatric patients be brought up to date with all immunisations in agreement with current immunisation guidelines. *Excipients:* Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **INTERACTIONS** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **PREGNANCY AND LACTATION** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **SIDE EFFECTS Refer to SmPC for complete information on side effects** *Very Common (≥ 1/10):* upper respiratory tract infection; *Common (≥1/100):* bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, Leukopenia (including neutropenia), anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma, hepatosplenic T-cell lymphoma*, leukopenia, thrombocytopaenia, pancytopaenia, aplastic anaemia, agranulocytosis, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. *Observed with other TNF-blocking agents. *Paediatric population: pJIA:* The safety of golimumab has been studied in a phase III study of 173 pJIA patients from 2 to 17 years of age. The average follow-up was approximately two years. In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies. **PACKAGE QUANTITIES** 1 x 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number** 50 mg Pre-filled Pen EU/1/09/546/001 50 mg Pre-filled Syringe EU/1/09/546/003 100 mg Pre-filled Pen EU/1/09/546/005 **Marketing Authorisation Holder** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands **Date of Revision of Text:** September 2018 Simponi/PI-IRE/09-18 © Merck Sharp & Dohme Ireland (Human Health) Limited 2018. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-2998700) **Date of preparation:** March 2019

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie.
Adverse events should also be reported to MSD (Tel: 01-2998700)

References: 1. Huynh, T.K. et al. Preferences of patients and health professionals for route and frequency of administration of biologic agents in the treatment of rheumatoid arthritis. Patient Preference and Adherence, 2014:8; 93-99. 2. Keystone EC, Genovese MC, Hall S et al. Safety and efficacy of subcutaneous golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: final 5-year results of the GO-FORWARD trial. J Rheumatol. 2016;43:298–306.
*Rheumatoid arthritis patients preferring subcutaneous therapies

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Leopardstown, Dublin D18 X5K7 Ireland

monthly Simponi® golimumab

IE-GOL-00001

the pathogenesis of inflammatory arthritis and rheumatic diseases. She has established strong collaborative research networks across Europe, USA and Singapore. Professor Fearon, has been awarded significant research funding from Arthritis-Ireland, Health Research Board, Science Foundation Ireland, IRCSET, European-ASPIRE, JU Innovative Medicines Initiative (IMI) and Maeve Binchy Funding for Arthritis Research, in addition to industry collaborative partnerships. She has published extensively in high impact peer-reviewed journals, and her research has been awarded several National/ International awards.

Dr Claire Sheehy

Dr Claire Sheehy is a Consultant Rheumatologist in University Hospital Waterford. A graduate of Trinity College Dublin, she completed the higher specialist training in rheumatology and general medicine, and was awarded an MD for work exploring the role of anti TNF therapy in early rheumatoid arthritis. She undertook a fellowship in connective tissue disease and vasculitis between Norfolk and Norwich University Hospital, and Addenbrookes Hospital. She took up her post in 2012; her current clinical interests include early inflammatory arthritis and connective tissue disease.

Dr Orla Killeen

Dr Orla Killeen qualified from UCG (NUI) Galway in 1996. She trained in General Paediatrics in Our Lady's Hospital for Sick Children, Crumlin and in Temple Street University Hospital, Dublin before sub-specialising in Paediatric Rheumatology. She undertook her paediatric rheumatology training at Great Ormond Street Children's Hospital, London and went on to complete a Barbara Ansell Fellowship in Paediatric Rheumatology in the Royal Hospital for Sick Children, Glasgow. She was appointed as Ireland's first Paediatric Rheumatologist in 2004, and is based at Our Lady's Children's Hospital, Crumlin and St Vincent's University Hospital, Dublin since July 2006. She is the Clinical lead for the National Centre for Paediatric Rheumatology (NCPR), providing care for patients both on a local and national level up to 18 years of age. Her areas of interest include Adolescent Rheumatology Transition Care as well as JIA, Down's arthropathy and Auto-Inflammatory syndromes.

Dr Bernadette Lynch

Dr Bernadette Lynch graduated from the Royal College of Surgeons in Ireland in 2003. She completed her higher specialist training in Rheumatology and General Medicine in 2013 having worked and studied in Dublin, Galway and London. She was awarded an MD from University College Dublin in 2011 for work on IL-22 and musculoskeletal ultrasound in Inflammatory Arthritis. She undertook a fellowship in Scleroderma and Vasculitis at the Royal Free Hospital Hampstead under Professor Chris Denton and Dr Aine Burns. During this time, Bernadette was part of the UK Scleroderma Study Group (UKSSG) which developed the national guidelines on the management of complications of Scleroderma. She took up her current appointment as Consultant Rheumatologist and General Physician in University Hospital Galway in 2015. Her principal clinical and academic interests are Scleroderma and Inflammatory Arthritis.

Dr Aine Gorman

Aine Gorman is a graduate of NUIG, completing her undergraduate studies in 2011 later undertaking basic specialist training at St James's Hospital. She entered Higher Specialist Training in Rheumatology in 2016. Now representing the SpR group on the Board of ISR.

Dr Adrian Pendleton
Consultant Rheumatologist
Musgrave Park Hospital, Belfast

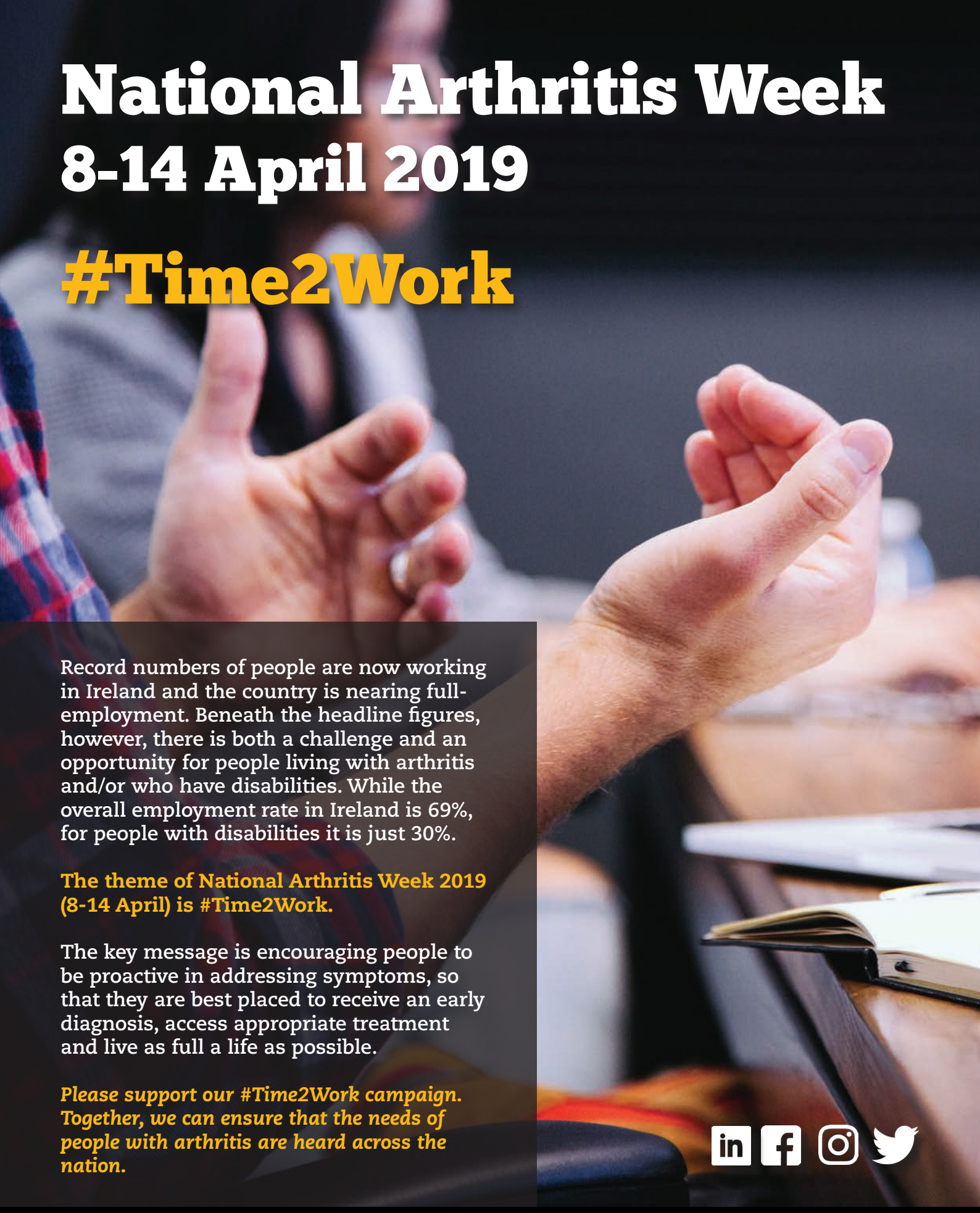
Dr Adrian Pendleton is a Consultant Rheumatologist and Clinical Lead for Rheumatology in the Belfast Health and Social Care Trust. Dr Adrian Pendleton trained in both Rheumatology and General Internal Medicine in Belfast and Nottingham. He was first appointed as a consultant Rheumatologist at the Queens Medical Centre, Nottingham University Hospitals before returning to the Belfast Trust Health and Social care Trust. Dr Pendleton is a Fellow of the Royal College of Physicians of Edinburgh and a Fellow of the Royal College of Physicians of Ireland and a Fellow of the British Society for Sport and Exercise Medicine (BASM). He is currently the Regional Specialty Advisor for Rheumatology with the Joint Royal College Physicians Training Board. Dr Pendleton has many research interests which include Early diagnosis and management of inflammatory arthritis, use of musculoskeletal ultrasound in Inflammatory arthritis, vasculitis and soft tissue injury.

Dr Bryan Whelan

Dr Bryan Whelan is a Consultant Rheumatologist in Our Lady's Hospital in Manorhmailton, Co Leitrim and an Honourary Senior Lecturer in Medicine in NUIG. He qualified from UCD in 2000 and completed BST in the Mater Hospital in Dublin. He completed SpR training in Rheumatology in CUH, the Mater Hospital and University College London. He has an MD and Masters Sports and Exercise Medicine from UCC and an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine. He is currently a board member of Arthritis Ireland, the SUH Research and Education Foundation, a member of the Academic Committee of the FSEM and a member of the Advisory Committee for Human Medicines Clinical Trials Subcommittee of the HPRA. His current research interests include muscle disease, exercise in rheumatology and osteoarthritis.

National Arthritis Week
8-14 April 2019

#Time2Work



Record numbers of people are now working in Ireland and the country is nearing full-employment. Beneath the headline figures, however, there is both a challenge and an opportunity for people living with arthritis and/or who have disabilities. While the overall employment rate in Ireland is 69%, for people with disabilities it is just 30%.

The theme of National Arthritis Week 2019 (8-14 April) is #Time2Work.

The key message is encouraging people to be proactive in addressing symptoms, so that they are best placed to receive an early diagnosis, access appropriate treatment and live as full a life as possible.

Please support our #Time2Work campaign. Together, we can ensure that the needs of people with arthritis are heard across the nation.

Arthritis Ireland
www.arthritisireland.ie
Helpline 01 661 8188 & **1890 252 846**

Arthritis Ireland

IRHPS Spring 2019 Update

Welcome to the Spring Conference 2019.

Firstly I would like to extend my thanks to the ISR and also to the Pharma companies for their continued support towards a wide range of educational opportunities through our bursaries.

We had a very successful meeting in Naas last September with presentations by Dr Valerie Rogers, Consultant Rheumatologist, University Hospitals Bristol, Romayne Orr – Advance Clinical OT, South Eastern Trust, Belfast and Edel Carberry and Rosalind Peart from Our Lady's Hospital Crumlin, Dublin with a focus on adolescent rheumatology.

The 2 highest scoring IRHPS abstract submissions also presented their work – many thanks to Geraldine Byrne and Yvonne Codd.

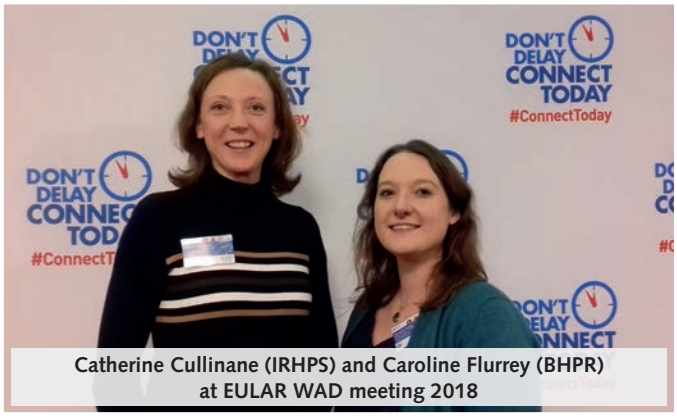
Congratulations also to our poster prize winners Madeline O'Neill, Oriel Corcoran, Noralee Kennedy and Nicole O'Keeffe and also to Bindu Irudayaraj, Jennifer Ashton and Catherine Cullinane who won our Janssen educational bursary.

Remember Health Professionals that this is your society and if you have any topics you would like covered in future meetings; please contact us via our e-mail edofficer@irhps.ie.

Also keep an eye on our website www.irhps.ie for news and meetings.

Trish Fitzgerald
IRHPS Chair

www.irhps.ie



Catherine Cullinane (IRHPS) and Caroline Flurrey (BHPR) at EULAR WAD meeting 2018

Geraldine Byrne, receiving IRHPS Educational Award 2018

Yvonne Codd, receiving IRHPS Educational Award 2018

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Treat to target. Daily.[1,2]

ADENURIC 80 mg and 120 mg film-coated tablets: Abbreviated Prescribing Information Please consult the Summary of Product Characteristics (SmPC) for full prescribing information. **Presentation:** Film-coated tablets containing 80 mg or 120 mg febuxostat. Also contains lactose monohydrate. **Use:** Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis) in adults. **Dosage and administration:** Oral use with or without food. Recommended dose is 80 mg once daily. If serum uric acid is > 6 mg/dL (357 µmol/L) after 2-4 weeks, 120 mg once daily may be considered. *Older people:* No dose adjustment required. *Renal impairment:* No dosage adjustment necessary in patients with mild or moderate renal impairment. Efficacy and safety not fully evaluated in patients with severe renal impairment. *Hepatic impairment:* Recommended dosage in patients with mild hepatic impairment is 80 mg. Limited information available in patients with moderate hepatic impairment. Efficacy and safety has not been studied in patients with severe hepatic impairment. *Children and adolescents:* Safety and efficacy in children under 18 has not been established. *Organ transplant recipients:* No experience therefore not recommended. **Contra-indications:** Hypersensitivity to the active ingredient or to any of the excipients. **Warnings and precautions:** *Cardio-vascular disorders:* Not recommended in patients with ischaemic heart disease or congestive heart failure. *Product allergy/hypersensitivity:* Advise patients of signs/symptoms of allergic/hypersensitivity reactions and monitor closely for symptoms. Stop treatment immediately if serious reactions occur, including Stevens-Johnson syndrome, Toxic epidermal necrolysis and acute anaphylactic reaction/shock; do not re-start febuxostat at any time. Severe hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with fever, haematological, renal or hepatic involvement in some cases. *Acute gouty attacks (gout flare):* Do not start treatment until an acute attack of gout has completely subsided. As with other urate lowering medicinal products, gout flares may occur during initiation of treatment. At treatment initiation flare prophylaxis for at least 6 months with an NSAID or colchicine is recommended. If a gout flare occurs during treatment, do not discontinue. Manage the gout flare concurrently as appropriate. Continuous treatment decreases frequency and intensity of gout flares. *Xanthine deposition:* As with other urate lowering medicinal products, in patients in whom the rate of urate formation is greatly increased (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome), the absolute concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract. As there has been no experience of treating gout in these patients with febuxostat such use is not recommended. *Mercaptopurine/azathioprine:* Not recommended in patients concomitantly treated with mercaptopurine/azathioprine. Where combination cannot be avoided, monitor patients closely. Dose reduction for mercaptopurine/azathioprine is recommended. *Theophylline:* No pharmacokinetic interaction shown with febuxostat 80 mg, no data for 120 mg. *Liver disorders:* Liver function test is recommended prior to the initiation of therapy and periodically thereafter based on clinical judgement. *Thyroid disorders:* Caution in patients with alteration of thyroid function. *Lactose:* Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.**Interactions:** *Mercaptopurine/azathioprine:* On the basis of the mechanism of action of febuxostat on xanthine oxidase inhibition concomitant use is not recommended. Where the combination cannot be avoided see SmPC for dosing instructions. *Rosiglitazone/CYP2C8 inhibitors:* No dosage adjustment required. *Theophylline:* No special caution advised for 80 mg febuxostat, no data available for 120 mg. *Naproxen and other inhibitors of glucuronidation:* Can be co-administered with naproxen with no dose adjustments necessary. *Inducers of glucuronidation:* Monitoring of serum uric acid is recommended 1-2 weeks after start of treatment with a potent inducer of glucuronidation. Cessation of treatment of an inducer might lead to increased plasma levels of febuxostat. *Colchicine/indometacin/hydrochlorothiazide/warfarin:* Can be co-administered with colchicine or indomethacin with no dose adjustments necessary. No dose adjustment necessary when administered with hydrochlorothiazide. No dose adjustment necessary for warfarin when administered with febuxostat. *Desipramine/CYP2D6 substrates:* Co-administration with other CYP2D6 substrates is not expected to require any dose adjustment for those compounds. *Antacids:* May be taken without regard to antacid use. **Pregnancy and lactation:** Do not use during pregnancy or breast-feeding. Effect on fertility unknown. **Side-Effects:** *Clinical Studies and post-marketing experience:* Common (1-10%): Gout flares, headache, diarrhoea*, nausea, liver function test abnormalities*, rash, oedema. Uncommon (0.1–1%): Blood thyroid stimulating hormone increased, diabetes mellitus, hyperlipidemia, decrease appetite, weight increase, decreased libido, insomnia, dizziness, paraesthesia, hemiparesis, somnolence, altered taste, hypoaesthesia, hyposmia, atrial fibrillation, palpitations, ECG abnormal, hypertension, flushing, hot flush, dyspnoea, bronchitis, upper respiratory tract infection, cough, abdominal pain, abdominal distension, gastro-oesophageal reflux disease, vomiting, dry mouth, dyspepsia, constipation, frequent stools, flatulence, gastrointestinal discomfort, cholelithiasis, dermatitis, urticaria, pruritus, skin discolouration, skin lesion, petechiae, rash macular, rash maculopapular, rash papular, arthralgia, arthritis, myalgia, musculoskeletal pain, muscle weakness, muscle spasm, muscle tightness, bursitis, renal failure, nephrolithiasis, haematuria, pollakiuria, proteinuria, erectile dysfunction, fatigue, chest pain, chest discomfort, blood amylase increase, platelet count decrease, WBC decrease, lymphocyte count decrease, blood creatine increase, blood creatinine increase, haemoglobin decrease, blood urea increase, blood triglycerides increase, blood cholesterol increase, haematocritic decrease, blood lactate dehydrogenase increased, blood potassium increase. Rare (0.1-0.01%): Pancytopenia, thrombocytopenia, agranulocytosis**, anaphylactic reaction**, drug hypersensitivity**, blurred vision, weight decrease, increase appetite, anorexia, nervousness, tinnitus, pancreatitis, mouth ulceration, hepatitis, jaundice**, liver injury**, Toxic epidermal necrolysis**, Stevens-Johnson Syndrome**, DRESS**, angioedema**, generalized rash (serious)**, erythema, exfoliative rash, rash follicular, rash vesicular, rash pustular, rash pruritic**, rash erythematous, rash morbillifom, alopecia, hyperhidrosis, rhabdomyolysis**, joint stiffness, musculoskeletal stiffness, tubulointerstitial nephritis**, micturition urgency, thirst, blood glucose increase, activated partial thromboplastin time prolonged, red blood cell count decrease, blood alkaline phosphatase increase, blood creatine phosphokinase increase**. *Treatment-emergent non-infective diarrhoea and abnormal liver function tests in combined Phase III studies more frequent in patients concomitantly treated with colchicine. **Adverse reactions coming from post-marketing experience. Rare serious hypersensitivity reactions including Stevens-Johnson Syndrome and anaphylactic reaction/shock have occurred in post-marketing experience. Hypersensitivity reactions to febuxostat can be associated with the following symptoms: skin reactions characterised by infiltrated maculopapular eruption, generalised or exfoliative rashes, also skin lesions, facial oedema, fever, haematologic abnormalities such as thrombocytopenia, and single or multiple organ involvement (liver and kidney including tubulointerstitial nephritis). Gout flares commonly observed soon after treatment start and in first months. Frequency decreases after time. Gout flare prophylaxis is recommended. Please consult the SmPC for further information. **Pack sizes:** 80 mg and 120 mg tablets: 28 film-coated tablets. **Legal category:** POM **Marketing authorization number:** EU/1/08/447/001, 003, 014, 020. **Marketing authorization holder:** Menarini International Operations Luxembourg S.A., Avenue de la Gare, L-1611 Luxembourg, Luxembourg **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924 or may be found in the SmPC. **Last updated:** January 2019.

References: 1. Adenuric 80 mg SmPC. October 2018. **2.** Adenuric 120 mg SmPC. May 2018.

Date of item: February 2019
IR-ADEN-01-2019

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Professor David Kane

Cosentyx® ▼
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5-year clinical trial evidence[1,8,9]

- **Cosentyx® reduces the symptoms** of PsA and AS and **helps improve patients Quality of Life**[1-4]
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PsA = Psoriatic Arthritis
AS = Ankylosing Spondylitis

ABBREVIATED PRESCRIBING INFORMATION

▼ COSENTYX 150 mg solution for injection in pre-filled pen. This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** COSENTYX 150 mg solution for injection in pre-filled pen. **Therapeutic Indications:** The treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; the treatment, alone or in combination with methotrexate (MTX), of active psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate. **Dosage & Method of Administration:** *Plaque Psoriasis:* Recommended dose in adults is 300 mg given as two subcutaneous injections of 150 mg. Dosing at Weeks 0, 1, 2 3 and 4, followed by monthly maintenance dosing. *Ankylosing Spondylitis:* The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 3 and 4, followed by monthly maintenance dosing. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis or who are anti TNFα inadequate responders, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 3 and 4, followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For all other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg. For all of the above indications, available data suggest that a clinical response is usually achieved within 16 weeks of treatment. Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 16 weeks. The safety and efficacy in children below the age of 18 years have not yet been established. **Contraindications:** Severe hypersensitivity reactions to the active substance or to any of the excipients. Clinically important, active infection (e.g. active tuberculosis). **Warnings/Precautions:** *Infections:* Cosentyx has the potential to increase the risk of infections. Serious infections have been observed in patients receiving Cosentyx in the post-marketing setting. Infections observed in clinical studies are mainly mild or moderate upper respiratory tract infections such as nasopharyngitis not requiring treatment discontinuation. Non serious mucocutaneous candida infections more frequently reported for secukinumab than placebo in psoriasis clinical studies. Caution in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, close monitoring and discontinue treatment until the infection resolves. Should not be given to patients with active tuberculosis. Anti tuberculosis therapy should be considered prior to initiation in patients with latent tuberculosis. *Inflammatory bowel disease:* Cases of new or exacerbations of Crohn's disease and ulcerative colitis have been reported. Caution should be exercised when prescribing to patients with inflammatory bowel disease including Crohn's disease and ulcerative colitis. Patients should be closely monitored. *Hypersensitivity reactions:* In clinical studies, rare cases of anaphylactic reactions have been observed in patients receiving Cosentyx. If an anaphylactic or other serious allergic reactions occur, administration should be discontinued immediately and appropriate therapy initiated. *Latex-sensitive individuals:* The removable cap of the Cosentyx pre filled pen contains a derivative of natural rubber latex. *Vaccinations:* Live vaccines should not be given concurrently with Cosentyx. Patients may receive concurrent inactivated or non live vaccinations. *Concomitant immunosuppressive therapy:* Use in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. **Interactions:** Live vaccines should not be given concurrently with Cosentyx. In a study in subjects with plaque psoriasis, no interaction was observed between secukinumab and midazolam (CYP 3A4 substrate. No interaction seen when administered concomitantly with methotrexate (MTX) and/or corticosteroids. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. It is preferable to avoid the use of Cosentyx in pregnancy as there are no adequate data from the use of secukinumab in pregnant women. It is not known whether secukinumab is excreted in human milk. A decision on whether to discontinue breast feeding during treatment and up to 20 weeks after treatment or to discontinue therapy with Cosentyx must be made taking into account the benefit of breast feeding to the child and the benefit of Cosentyx therapy to the woman. The effect of secukinumab on human fertility has not been evaluated. **Undesirable Effects:** *Very common (≥1/10);* Upper respiratory tract infections. *Common (≥1/100 to <1/10);* Oral herpes, rhinorrhoea, diarrhoea, urticaria *Uncommon (≥1/1,000 to <1/100);* Oral candidiasis, tinea pedis, otitis externa, neutropenia, conjunctivitis. *Rare (≥1/10,000 to <1/1,000)* Anaphylactic reactions. Please see Summary of Product Characteristics for further information on undesirable effects. **Legal Category:** POM. **Marketing Authorisation Holder:** Novartis Europharm Ltd, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland. **Marketing Authorisation Numbers:** EU/1/14/980/004-005. **Date of Revision of Abbreviated Prescribing Information:** October 2018. Full prescribing information is available upon request from: Novartis Ireland Limited, Vista Building, Elm Park Business Park, Elm Park, Dublin 4. Tel: 01-2204100 or at www.medicines.ie. Detailed information on this product is also available on the website of the European Medicines Agency http://www.ema.europa.eu

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie E-mail: medsafety@hpra.ie. Adverse events should also be reported to Novartis Ireland by calling 01-2080 612 or by email to: drugsafety.dublin@novartis.com

References: 1. PJ Mease et al. Poster 2568. Presented at American College of Rheumatology Annual Meeting (ACR), 20-24 October 2018, Chicago, USA. **2.** Strand et al. Poster 2553. Presented at American College of Rheumatology Annual Meeting (ACR), 20-24 October 2018, Chicago, USA. **3.** H Marzo-Ortega et al. Poster 2556. Presented at American College of Rheumatology (ACR) Annual Meeting, October 19-24, 2018, Chicago, USA. **4.** A Deodhar et al. Poster 2583. Presented at American College of Rheumatology (ACR) Annual Meeting, October 19-24, 2018, Chicago, USA. **5.** McInnes et al. *Arthritis Research & Therapy* (2018) 20:113. **6.** Gossec et al. Poster SAT0463 presented at Annual European Congress of Rheumatology, 14-17 June 2017, Madrid, Spain. **7.** A Deodhar et al; *Clinical and Experimental Rheumatology* 2018. **8.** Baraliakos X et al. Abstract L13 presented at American College of Rheumatology (ACR) Annual Meeting, October 19-24, 2018, Chicago, USA. **9.** Bissonnette et al. Secukinumab demonstrates high sustained efficacy and a favourable safety profile in patients with moderate-to severe psoriasis through 5 years of treatment (SCULPTURE Extension Study); JEADV 2018.

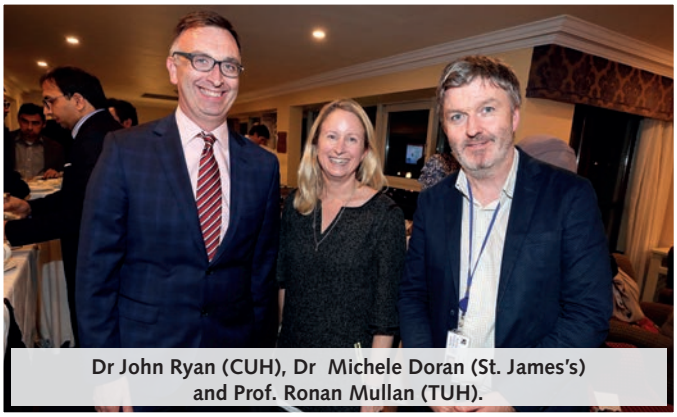
Date of Preparation: January 2019
IE02/COS19-CNF002

NOVARTIS

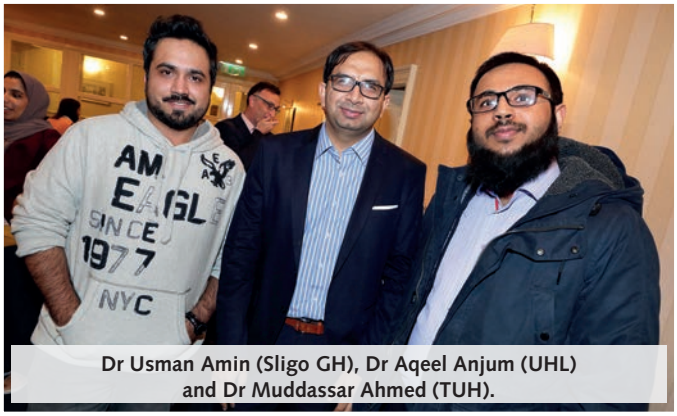
ACR Highlights Radisson Blu St Helens 2018

Oliver Kinlough, Deirdre Moran, Liz Moran (AbbVie) and Dr John Ryan

Dr Afra Aldhaheri (MMUH) and Dr Shamma Alnokhatha (TUH).



Dr John Ryan (CUH), Dr Michele Doran (St. James's) and Prof. Ronan Mullan (TUH).



Dr Usman Amin (Sligo GH), Dr Aqeel Anjum (UHL) and Dr Muddassar Ahmed (TUH).

Dr Kamal Osman (Beaumont Hospital) and Dr A.Abdalla (SVUH).

Prof. Ronan Mullan and Dr Yousef Alammari. (ISR Medal winner Best Oral Abstract).

Oliver Kinlough (AbbVie), Dr Alwin Sebastian, Dr Rachael Flood, Dr Sharon Crowley, Dr Colm Kirby and Hugh Sheehan (AbbVie)

Dr Valerie Rogers - IRHPS Meeting

Sp R Training Report 2018

The Higher Specialist Training Scheme in Rheumatology continues to attract high quality candidates.. 'On the job' learning is supplemented by dedicated training days held at sites throughout the country, with the annual ACR highlights meeting enabling Sp Rs to disseminate their key learning points to fellow trainees and trainers who were unable to attend the ACR.

This year we had the innovation of combining the Rheumatology and Dermatology Sp R's at our joint training day at the Clayton Hotel in Cork. This was hosted by Dr John Ryan NSD and Dr Michelle Murphy (Dermatology) - again delivered by the SO team who are now regarded as 'our human capability experts'. We now accept that we have discovered a totally different approach towards solving difficulties we encounter quite frequently. It was a very successful day which contained energy, humour and enjoyment in varying degrees. 30 Trainees attended.

There were expert presentations from Dr Maureen Gaffney, renowned Psychologist, Broadcaster, Author and Speaker. She was followed by Mr Peter Kidd, Pharmacist from Galway who spoke on "Efficiency Enhancement in a busy Hospital Unit" and Dr Len Harty spoke on his "Sp R Experience and ongoing education". The feedback from both groups of Sp R's was very positive

Both the ACR highlights and Innovation day have been made possible by unrestricted educational grants from AbbVie. AbbVie and Novartis have provided similar grants to support Webinar teaching sessions, which remain in a nascent form, but should go some way towards delivering a full curriculum of rheumatology teaching in the era of shift work and decreased rheumatology contact time for trainees particularly during their dual training years.

We are only now seeing the impact of the Imrie report and subsequent Keane review resulting in changes in how the general internal medicine training component is being delivered. This is an ongoing process, with greater scrutiny of the quality and safety of training sites by both the RCPI and Irish Medical Council (IMC). The IMC has only recently commenced site inspections and it remains to be seen how it chooses to exercise its considerable powers in this process.

Dr Maureen Gaffney

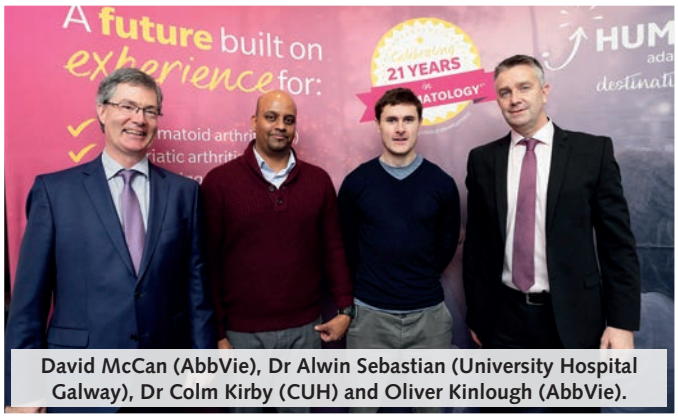
Aidan Moloney (AbbVie), Dr Lisa Roche (South Infirmary), Dr Eilis NicDhonncha (South Infirmary) and Oliver Kinlough (AbbVie).

Oliver Kinlough (AbbVie), David McCann (AbbVie), Dr Alwin Sebastian (University Hospital Galway) and Dr Fatemah Baron (University Hospital Galway).

Peter Kidd (University Hospital Galway), Dr Alwin Sebastian (University Hospital Galway) and Oliver Kinlough (AbbVie).

Sp R Training Report 2018

David McCan (AbbVie), Matt Spencer, Liz Evenden (SO Team), Aidan Moloney (AbbVie) and Oliver Kinlough (AbbVie)



David McCan (AbbVie), Dr Alwin Sebastian (University Hospital Galway), Dr Colm Kirby (CUH) and Oliver Kinlough (AbbVie).

Dr Cathal O'Connor (Waterford University Hospital), Dr Jennifer Boggs (Drogheda Hospital).

David McCan (AbbVie), Dr John Ryan (CUH), Dr Sinead Maguire (Waterford University Hospital) and Oliver Kinlough (AbbVie).

Dr Usman Amin (Sligo Hospital), Dr Carl Orr (Blanchardstown Hospital), Oliver Kinlough (AbbVie) and Dr John Ryan (CUH).

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(certolizumab pegol)

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1. Mariette X, et al. Ann Rheum Dis 2018; 77(2):228-233
2. CIMZIA® Summary of Product Characteristics

Cimzia®
Certolizumab Pegol
Active Ingredient: Pre-filled syringe and pre-filled pen contain 200 mg certolizumab pegol in one ml.Indication(s): Rheumatoid arthritis (RA): Cimzia, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Cimzia in combination with methotrexate (MTX), is also indicated in the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX. Axial spondyloarthritis: Cimzia is indicated for the treatment of adult patients with severe active axial spondyloarthritis, comprising: Ankylosing spondylitis (AS): Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). Axial spondyloarthritis without radiographic evidence of AS: Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs. Psoriatic arthritis: Cimzia in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Plaque psoriasis: Cimzia is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Dosage and Administration: Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Cimzia is indicated in adult patients. Patients should be given the special alert card. For RA and psoriatic arthritis MTX should be continued during treatment with Cimzia where appropriate.Loading dose: The recommended starting dose is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. Plaque psoriasis: the starting dose for adult is 400 mg every 2 weeks given at weeks 0, 2 and 4.Maintenance dose: RA and Psoriatic Arthritis: The recommended maintenance dose is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dose of 400 mg every 4 weeks can be considered. Axial spondyloarthritis: The recommended maintenance dose is 200 mg every 2 weeks or 400 mg every 4 weeks. For the above indications continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment. Plaque psoriasis: the recommended maintenance dose is 200 mg every 2 weeks. 400 mg every 2 weeks can be considered in patients with insufficient response. Missed dose: Advise patients to inject the next dose as soon as they remember and inject subsequent doses as originally instructed. Paediatric population (<18 years old): Not recommended. Consult SPC for further information. Contraindications: Hypersensitivity to the active substance or to any of the excipients; active tuberculosis or other severe infections such as sepsis or opportunistic infections; moderate to severe heart failure (NYHA classes III/IV).Precautions: Prior to treatment with Cimzia all patients to be appropriately screened for tuberculosis, e.g. tuberculin skin test and chest X-ray (local recommendations may apply) and results recorded on the patient alert card. False negative tuberculin skin test results are possible in severely ill or immunocompromised patients. Do not initiate treatment in cases of latent tuberculosis, clinically important active infection, including chronic or localised infections until the infection is controlled. In patients with a past history of latent tuberculosis use of anti-tuberculosis therapy must be started before initiation of Cimzia. Evaluate and monitor patients closely for signs and symptoms of infections including chronic and local infections and active and latent tuberculosis. Treatment must not be initiated until infection is controlled. Some patients who have been successfully treated for active tuberculosis have redeveloped tuberculosis while being treated with Cimzia. Monitor patients closely for signs of infection during and up to 5 months after treatment in order to minimise delay in diagnosis and treatment. Serious infections (including sepsis, tuberculosis, miliary tuberculosis, disseminated and extrapulmonary disease) and opportunistic infections (including histoplasmosis, nocardia, candidiasis) have been reported with some fatal outcomes. Caution is advised in patients with a history of recurring or opportunistic infections including those on concomitant corticosteroid or immunosuppressive medications or elderly. Patients should be tested for HBV infection before initiating treatment with Cimzia and if treated should be continually monitored. In patients receiving TNF antagonists, HBV reactivation has occurred in chronic carriers with some fatal outcomes. Cimzia should be discontinued and effective antiviral therapy and appropriate supportive treatments initiated. There is an increase in background risk for lymphoma and leukaemia in patients with long-standing highly active RA. Periodic skin examination is recommended particularly for patients with risk factors for skin cancer. Exercise caution when initiating TNF antagonist therapy in patients with a history of malignancies and when considering continuing treatment if patients develop lymphoma, leukaemia, mild congestive heart failure and demyelinating disorders such as multiple sclerosis. Advise patients to seek immediate medical attention if they develop signs and symptoms suggestive of tuberculosis, blood dyscrasias or infection. Discontinue treatment if patients develop significant haematological abnormalities including aplastic anaemia, leukopenia, pancytopenia, thrombocytopenia; lupus-like syndrome; mild congestive heart failure and demyelinating disorders such as multiple sclerosis. There is a potential risk of worsening of congestive heart failure with TNF antagonists including Cimzia. As for all TNF antagonists COPD and heavy smoking may put patients at greater risk of malignancies. Patients receiving Cimzia may receive vaccination except live vaccines. Live vaccines should not be administered concurrently with Cimzia. The 14 day half-life of certolizumab pegol should be taken into account prior to planned surgical procedures. Cimzia may cause erroneously elevated (aPTT) assay results in patients without coagulation abnormalities. Interactions: The combination of Cimzia and anakinra or abatacept is not recommended. Fertility, pregnancy and lactation: The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last Cimzia dose due to its elimination rate, but the need for treatment of the woman should also be taken into account. Cimzia should only be used during pregnancy if clinically needed. Cimzia can be used during breastfeeding. **Driving etc.:** Cimzia may have a minor influence on the ability to drive and use machines. Dizziness may occur following administration. Caution is advised. Adverse Effects: Common adverse-effects (≥ 1/100 to <1/10): Bacterial infections (including abscess) and viral infections (including herpes zoster, papillomavirus and influenza), eosinophilic disorders, leukopenia (including neutropenia, lymphopenia), headaches (including migraine), sensory abnormalities, hypertension, nausea, hepatitis (including hepatic enzyme increased), rash, pyrexia, pain (any site), asthenia, pruritus (any site), injection site reactions. Consult SPC in relation to other side effects. Pharmaceutical Precautions: Store in refrigerator (2°-8°C). Do not freeze. Keep the pre-filled syringe and pre-filled pen in the outer carton in order to protect from light. **Legal Category:** POM Marketing Authorisation Number(s): EU/1/09/544/001, EU/1/09/544/005 UK NHS Cost: £715 per pack of 2 pre-filled syringes or pens of 200 mg each Marketing Authorisation Holder: UCB Pharma S.A., Allée de la Recherche 60, 1070 Brussels, Belgium.

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Date of Revision: 05/2018 (UK/18CI0079).

Adverse events should be reported
Reporting forms and information can be found at: yellowcard.mhra.gov.uk
Adverse events should also be reported to UCB Pharma Ltd

IE-P-CZ-axSpA-1900001. March 2019

IRNF-ACR Highlights 2019

The second annual post ACR Highlights meeting took place on Friday 25th January in the Hilton Hotel, Kilmainham. It was attended by twenty-seven nurses from Rheumatology centres; practising in both outpatient and inpatient services, throughout the country.

The topics chosen were current, varied and covered areas that are encountered by Rheumatology Nurse's on a regular basis in clinical practice.

Osteoporosis Update:

Louise Murphy cANP Cork University Hospital

Louise started proceedings with a comprehensive presentation on the latest research and developments in the management of Osteoporosis.

Challenges facing the management of this condition were outlined and common tools used in forming a diagnosis, or identifying patients at risk were discussed. Current statistics demonstrate the increased risk of further fractures if treatment is not implemented.

A detailed account of how both traditional and contemporary treatments work were explained. Potential side effects and safety monitoring were also discussed. Information on sequential monotherapy was disseminated and options available post treatment with Bisphosphonates, PTH or Denosumab were explored in a highly engaging and interesting presentation.

"Beyond Treat to Target"

Noreen Harrington RANP Our Lady's Hospital Manorhamilton County Leitrim

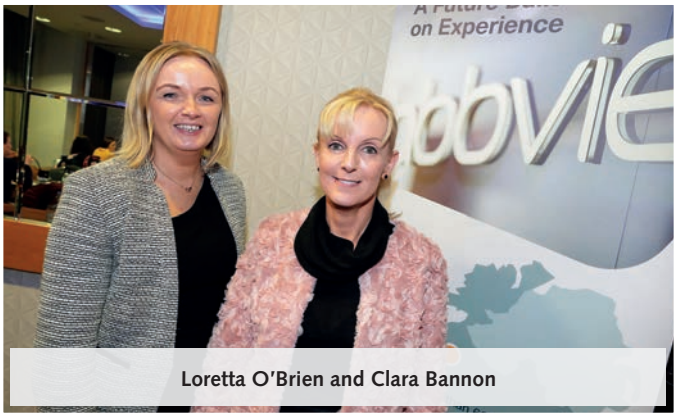
Treat to Target is a relatively new concept within our scope of practice. Noreen's excellent thought- provoking presentation focussed on "Beyond Treat to Target" covering pathogenesis, prediction, prevention, opportunities and challenges of Inflammatory Arthritis.

Incorporated into the presentation was identifying pre-clinical Rheumatoid Arthritis (RA) followed by an overview of RA development. This was followed by an insight into general concepts of prediction, predictive models, prospective studies and novel predictors. Prevention trials centred on different targets and different times in the stages of RA.

The presentation concluded with a focus on the opportunities and challenges in the prevention of RA. The take home message was to learn from clinical trials, the application of tried and tested technology to the pathogenesis of disease. The critical question posed was how long do we treat with drugs?

Stephanie Narramore, Joan Swan and Rebecca Griffin

Patricia Kavanagh and Karen Walsh



Loretta O'Brien and Clara Bannon

IRNF-ACR Highlights 2019

"Perioperative Management of Rheumatic Disease Patients:
Ann Maria Curran RANP Merlin Park Hospital Galway

Questions surrounding this subject are frequently asked of Rheumatology Nurses. In this concise presentation Ann Maria clarified such questions and explained the rationale behind the decisions.

A variety of rheumatology conditions and a number of different orthopaedic surgeries were outlined. In this insightful presentation outcomes of care for these different cohorts of patients were compared.

Infection risks were highlighted comprehensively, in addition to this, other potential complications to include Sepsis, Pulmonary Embolism and Renal Failure were alluded to.

The holding of different groups of medications in the perioperative stage to include DMARDs, Biologics and Glucocorticoids was raised, in particular the rational for holding such medications; the flare v infection risk was outlined. Finally, the administration of such medications and the effect on wound healing were discussed.

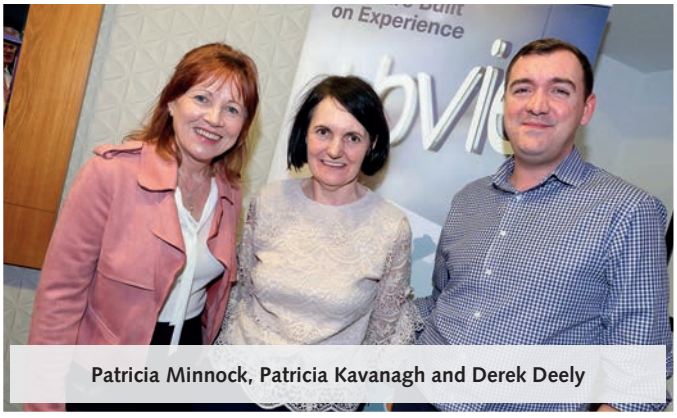
In summary the presentation highlighted the importance of an MDT approach in the management of unique perioperative challenges and that further studies are required.


Mary Gillespie, Louise Murphy and Aileen Woods


Liz Moran and Martina Corbett


Alexia Kelly and Patricia O'Neill


Ann O'Riordan and Trish Cregan


Patricia Minnock, Patricia Kavanagh and Derek Deely

IRNF-ACR Highlights 2019

Noreen Harrington, Patricia Kavanagh, Ann Maria Curran and Louise Murphy

"Get the most from Methotrexate and other conventional DMARD's Without causing harm"
Patricia Kavanagh RANP Mater Misericordiae University Hospital Dublin

The majority of Rheumatology Nurses are involved in Early Arthritis or Treat to Target clinics. Disease Modifying Arthritic Drugs (DMARDs) are initiated in this cohort of patients. This topic was chosen on the background of the aforementioned. The focus of the individual DMARD's discussed was obtaining best clinical outcomes while avoiding toxicity.

Although the presentation focussed primarily on Methotrexate, Salazopyrin and Hydroxychloroquine were also discussed. Incorporated in the component on Hydroxychloroquine were aspects of another ACR presentation. "The Great Debate": Guidelines for SLE: Hydroxychloroquine Dose should be no more than 5mg/kg in all patients.

A lively discussion followed the presentations and there was good interaction from the audience.

On behalf of all members of the IRNF I would sincerely like to thank Abbvie for continuing to support this meeting. Sincere gratitude is extended to Michael Dineen for facilitating the meeting.

Last but by no means least my fellow presenters who not alone placed a great deal of thought and time into their presentations but delivered them splendidly; showcasing such command of their chosen topics. To all the nurses who attended on the evening your enthusiasm and support were very much appreciated. Thank you.

Patricia Kavanagh RANP

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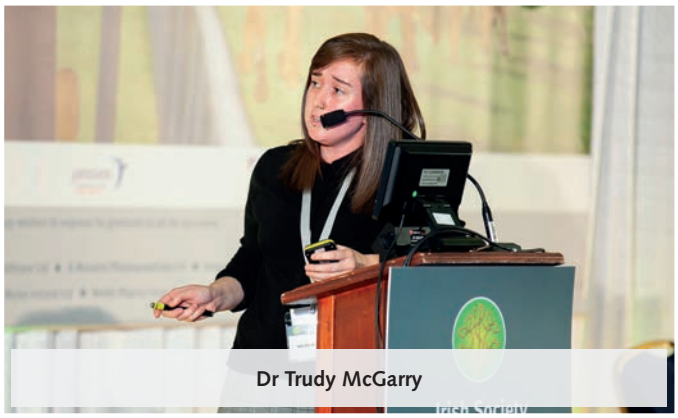
ISR Autumn Meeting 2018

Dr Anthony O'Connor, MSD Satellite Meeting

Professor Trevor Duffy, MSD Satelitte Meeting



Dr Trudy McGarry

Dr Emma Dorris

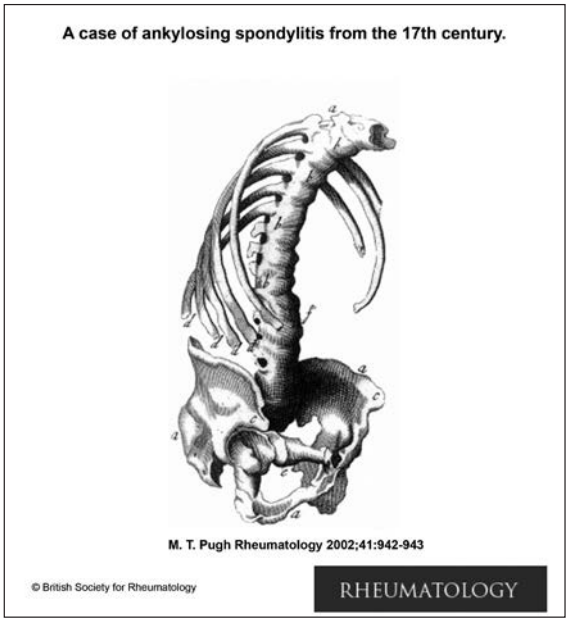
Dr Charlene Foley

Dr Megan Hanlon

Dr Yousef Alammari

Dr Gillian Fitzgerald

ISR Bernard Connor Medal



The Irish Society for Rheumatology (ISR) has established the Connor Medal to encourage medical student participation in rheumatology during their undergraduate education and to support student engagement with the activities of the Irish Society for Rheumatology, including sponsorship of student attendance at the ISR Annual Scientific Meeting.

The award is open to all students of medicine who fulfil the eligibility criteria below. In addition to receiving the Connor Medal, the winner will be invited to attend the annual scientific meeting of the ISR to present their work to the membership, as a guest of the society. Additionally, and at the discretion of the judging panel, up to two runners-up may be awarded full registration to attend the ISR annual scientific meeting.

Bernard Connor

The Connor Medal is named in honour of Bernard Connor, an Irish physician who observed and described the characteristic skeletal and clinical features of Ankylosing Spondylitis in 1693, while himself a medical student in Paris. This award will be made annually on the basis of competitive submission.

Submission Categories

Eligible students are invited to submit original work in one of the following three categories. Only one submission per student will be accepted.

1. Original Research

Please submit your original research (e.g. clinical, laboratory, epidemiology etc.) as an abstract in the usual scientific format plus a short section on your observation/interpretation of the work: the abstract should be subdivided into Aim, Methods, Results & Conclusions. The text of the abstract must not exceed 250 words (excluding title, authors, and any references). One supplementary figure or table may be provided as an attachment for illustrative purposes.

2. Essay

Examples of such work might include a review of a clinical or scientific topic in rheumatology; a reflective essay on your experiences of rheumatology as a medical student or other original writing which addresses the theme of medical observation in rheumatology. (max 1500 words)

3. Case Report

These should be submitted in full form and present the details of an interesting case followed by a discussion on your observations of the key points of interest. These should be submitted in full (max 800 words, concluding with summary key message).

Eligibility

1. a) Applicants must be fully registered students of a Medicine Programme (MB degree) in an Irish University (NUIG, QUB, RCSI, TCD, UCC, UCD, UL) on 1 April 2019

OR

2. b) Irish citizens who are fully registered students of an MB programme in a university outside Ireland on 1 April 2019
3. c) Original work submitted must have been carried out while a student of Medicine (i.e. not during a prior degree, course of study or period of employment).
4. d) Applicants must submit completed entries to the ISR by the notified deadline.
5. e) In the case of original research, applicants must have made a significant contribution to the work submitted and this must be verified by the supervising academic/ rheumatologist who shall co-sign the application form.

How to Apply

Download the Application Form for the Connor Medal, from the ISR website: www.isr.ie, fully complete the form, and return together with your submission to info@isr.ie.

Closing Date

1 July 2019

Judging Criteria

The Medal will be awarded according to the criteria below which will be applied to all submissions in all categories.

- Student's contribution to the work
- Relevance of the submitted work to rheumatology
- Originality and Merit of the work

ISR Bernard Connor Medal Winner 2018

Dylan McGagh
University of Oxford
"Could patient-reported outcomes help to inform a holistic treat-to-target approach in rheumatology"

Prescribing Information
Humira (adalimumab) 20mg and 40mg solution for injection in pre-filled syringe, Humira 40mg solution for injection in pre-filled pen, Humira 40mg/0.8ml solution for injection (vial) and Humira 80mg solution for injection in pre-filled pen. Refer to Summary of Product Characteristics (SmPC) for full information. Presentation and method of administration: Each single dose 0.2 ml pre-filled syringe contains 20 mg of adalimumab for subcutaneous injection. Each single dose 0.4 ml pre-filled pen, 0.4 ml pre-filled syringe or 0.8 ml vial contains 40mg of adalimumab for subcutaneous injection. Each single dose 0.8 ml pre-filled pen contains 80 mg of adalimumab for subcutaneous injection.**Indications and Dosage:** Humira 20mg pre-filled syringe, Humira 40 mg vial and Humira 80 mg pen are only approved for use in specific indications with a therapeutic requirement, **please refer to SmPCs for full information**. Humira treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Humira is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Humira. Patients treated with Humira should be given the special alert card. After proper training in injection technique, patients may self- inject with Humira if their physician determines that it is appropriate and with medical follow-up as necessary. During treatment with Humira, other concomitant therapies (e.g., corticosteroids and/or immunomodulatory agents) should be optimised. **Rheumatoid arthritis (RA), adults:** In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX. In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces rate of progression of joint damage on X-ray and improves physical function, in combination with MTX. Dosage: 40 mg single dose every other week (EOW). Concomitant MTX should be continued. In monotherapy, patients may require 40 mg every week or 80mg EOW if they experience a decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose interruption, e.g. before surgery or if serious infection occurs. Reintroduction of Humira after discontinuation for 70 days or longer gave same magnitudes of clinical response and similar safety profile as before dose interruption. **Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above:** In combination with MTX, for active pJIA, with inadequate response to one or more DMARDs. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Dosage: 10 kg to <30 kg: 20 mg EOW. If ≥ 30 kg: 40 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Enthesitis-related arthritis (ERA), paediatrics 6 years and above:** For active ERA with inadequate response or intolerance to conventional therapy. Dosage: 15 kg to < 30 kg: 20 mg EOW. If ≥ 30 kg: 40 mg EOW. **Ankylosing spondylitis (AS), adults:** For severe active AS with inadequate response to conventional therapy. Dosage: adults: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults:** For severe nr-axSpA with objective signs of inflammation (elevated CRP and / or MRI), and an inadequate response to, or intolerance to nonsteroidal anti-inflammatory drugs. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriatic arthritis (PsA), adults:** For active and progressive PsA with inadequate response to DMARDs. Reduces rate of progression of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function. Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriasis (Ps), adults:** For moderate to severe chronic plaque psoriasis in candidates for systemic therapy. Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. Beyond 16 weeks, patients with inadequate response can increase dosage to 40 mg every week or 80mg EOW (refer to SmPC). If adequate response is achieved with 40mg every week or 80mg EOW, dosage may subsequently be reduced to 40 mg every other week. **Psoriasis, paediatrics 4 years and above:** For severe chronic plaque psoriasis with inadequate response to or if topical therapy and phototherapies are inappropriate. Dosage: 15 kg to < 30 kg: 20 mg dose initially followed by 20 mg EOW starting one week after initial dose. If ≥ 30 kg: 40 mg dose initially followed by 40 mg EOW starting one week after initial dose. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. **Hidradenitis suppurativa (HS), adults and adolescents from 12 years of age:** For active moderate to severe HS (acne inversa) in patients with an inadequate response to conventional systemic HS therapy. Dosage: HS, adults: 160 mg dose initially at Day 1, followed by 80 mg two weeks later at Day 15. Two weeks later (Day 29) continue with a dose of 40 mg every week or 80mg EOW. Reintroduction after treatment interruption: 40 mg every week or 80 mg EOW. Dosage: HS, adolescents from 12 years and ≥30 kg: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. If there is inadequate response to 40 mg EOW, an increase in dosage to 40 mg every week or 80mg EOW may be considered. Treatment interruption: Humira may be re-introduced as appropriate. Adults and adolescents from 12 years of age: Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions is recommended to be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no improvement in that time. Evaluate periodically the benefit and risk of continued long-term treatment. **Crohn's disease (CD), adults:** For moderately to severely active CD in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and /or an immunosuppressant, or are intolerant to or have medical contraindications for such therapies. Dosage: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If decrease in clinical response, can increase dosage to 40 mg every week or 80mg EOW. Patients with no response by Week 4 may benefit from continued maintenance therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Paediatric Crohn's disease (CD), 6 years and above:** For moderately to severely active CD with inadequate response to, intolerance to or contraindication for conventional therapy including primary nutrition therapy and a corticosteroid, and/or an immunomodulator. Dosage: < 40 kg: Induction: 40 mg dose at Week 0, followed by 20 mg at Week 2. For a more rapid response: 80 mg at Week 0, followed by 40 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 20 mg dose EOW. If insufficient response, consider an increase in dosage to 20 mg every week. If ≥ 40 kg: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. If insufficient response, consider an increase in dosage to 40 mg every week or 80 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Ulcerative colitis (UC), adults:** For moderately to severely active UC with inadequate response to, intolerance to or contraindication for conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA). Dosage: Induction: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If insufficient response, consider an increase in dosage to 40 mg every week or 80mg EOW. Treatment beyond 8 weeks should be reconsidered if no clinical response in that time. **Uveitis, adults:** For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Humira. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. **Paediatric Uveitis, 2 years and above:** For chronic non-infectious anterior uveitis with inadequate response or intolerance to conventional therapy, or in whom conventional therapy is inappropriate. Dosage: < 30 kg: 20 mg dose EOW in combination with MTX. Optional 40 mg loading dose one week prior to start of maintenance therapy. No clinical data in use of loading dose < 6 years of age (see SmPC). If ≥ 30 kg: 40 mg dose EOW in combination with MTX. Optional 80 mg loading dose one week prior to start of maintenance therapy. Evaluate on a yearly basis the benefit and risk of continued long-term treatment. **Contraindications:** Hypersensitivity to the active substance or any of the excipients (see

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- ✓ Rheumatoid arthritis (RA)
- ✓ Psoriatic arthritis (PsA)
- ✓ Ankylosing spondylitis (AS)
- ✓ Non-radiographic axial spondyloarthritis (nrAxSpA)
- ✓ Polyarticular juvenile idiopathic arthritis (P-JIA)
- ✓ Enthesitis-related arthritis (ERA)

HUMIRA® in combination with methotrexate, is indicated for the treatment of:[2]

- Moderate to severe, active **rheumatoid arthritis** in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- Severe, active and progressive **rheumatoid arthritis** in adults not previously treated with methotrexate.
- Active **polyarticular juvenile idiopathic arthritis**, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.

HUMIRA® can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

HUMIRA® is indicated for the treatment of:[2]

- Adults with severe active **ankylosing spondylitis** who have had an inadequate response to conventional therapy.
- Active and progressive **psoriatic arthritis** in adults when the response to previous disease-modifying anti rheumatic drug therapy has been inadequate.
- Adults with severe **axial spondyloarthritis without radiographic evidence of AS** but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.
- Active **enthesitis-related arthritis** in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

SmPC). Active tuberculosis (TB) or other severe infections such as sepsis and opportunistic infections; Moderate to severe heart failure (NYHA class III/IV). **Warnings and precautions:** Clearly record trade name and batch number of administered product to improve traceability of biological medicinal products. ***Infections:*** Patients taking Tumour Necrosis Factor (TNF)-antagonists are more susceptible to serious infections especially if impaired lung function. Monitor for infections, including TB, before, during and for 4 months after treatment. Do not initiate treatment with an active infection, until it is controlled. Consider risk/benefit prior to treatment in patients exposed to high risk of TB or who have travelled in areas of high risk of TB or endemic mycoses. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis, and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections, including the use of concomitant immunosuppressive medications. ***Serious infections:*** Serious infections, including those with hospitalisation or death reported in patients receiving treatment. ***TB:*** Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (disseminated) reported. Screen all patients before therapy initiation for active or latent TB. Appropriate screening tests (i.e. tuberculin skin test and chest X-ray) should be performed in all patients. If active TB is diagnosed Humira therapy must not be initiated. If latent TB is suspected, consult a physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Humira. Despite prophylaxis, TB reactivation has occurred on Humira. ***Other opportunistic infections:*** Opportunistic infections observed in patients receiving Humira. Stop treatment in patients with signs and symptoms of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients. ***Hepatitis B Reactivation:*** Reactivation of HBV has occurred in chronic carriers (surface antigen positive). Patients should be tested for HBV infection before initiating treatment. HBV carriers should consult with a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of Humira. If reactivation occurs stop treatment and initiate appropriate anti-viral and supportive treatment. ***Neurological events:*** Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinuation of treatment should be considered if any of these disorders develop. Neurological evaluation should be performed in patients with non-infectious intermediate uveitis before therapy initiation and regularly during treatment, to assess for pre-existing or developing central demyelinating disorders. ***Allergic reactions:*** Reports of serious allergic reactions including anaphylaxis received. For serious allergic or anaphylactic reaction, stop Humira immediately and initiate appropriate therapy. ***Malignancies and lymphoproliferative disorders:*** A possible risk of malignancy, including lymphoma and leukaemia, in all patients including paediatric patients, treated with TNF antagonists. Examine all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment for non- melanoma skin cancer prior to and during treatment, caution in COPD patients, and in patients with increased risk of malignancy due to heavy smoking. Consider the potential risk with the combination of AZA or 6-MP and Humira (hepatosplenic T-cell lymphoma has occurred). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk of developing dysplasia or colon cancer is unknown. Patients with UC, history of dysplasia or colon carcinoma to be screened for dysplasia before and during treatment. ***Haematologic reactions:*** Adverse events of the haematologic system reported with Humira. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias develop while on treatment. ***Vaccinations:*** Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to Humira treatment ***Congestive heart failure:*** See contraindications. Caution is advised in mild heart failure (NYHA class I/II). Discontinue treatment for new or worsening symptoms of congestive heart failure. ***Autoimmune processes:*** Autoimmune antibodies may form with Humira. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. ***Surgery:*** Consider the long half-life of Humira for planned surgical procedures. Closely monitor for infections. ***Small bowel obstruction:*** Failure to respond to treatment for CD may indicate the presence of fixed fibrotic stricture requiring surgical treatment. ***Elderly:*** Serious infections were higher in patients over 65 years of age, some of which had a fatal outcome. Consider risk of infections in these patients. ***Interactions:*** Antibody formation was lower when Humira was given together with MTX in comparison with use as monotherapy. Combination of Humira with other biologic DMARDS (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. ***Fertility, pregnancy and lactation:*** Humira should only be used during pregnancy if needed. Women of childbearing potential should consider the use of adequate contraception and continue its use for at least five months after the last Humira treatment. No administration of live vaccines (e.g. BCG) to infants exposed to Humira in utero for 5 months following mother's last Humira treatment during pregnancy. Humira can be used during breast-feeding. ***Adverse Reactions:*** *Very common* ≥ 1/10: Respiratory tract Infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leukopenia (including neutropenia and agranulocytosis), anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction (including injection site erythema). **Serious, including fatal, adverse reactions have been reported.** including infections/sepsis, TB, opportunistic infections, allergic reactions (including anaphylaxis), HBV reactivation and malignancies (including leukaemia, lymphoma and hepatosplenic T-cell lymphoma). Serious haematological, neurological and autoimmune reactions have also been reported. These include rare reports of pancytopenia, aplastic anaemia, central and peripheral demyelinating events and reports of lupus, lupus-related conditions and Stevens-Johnson syndrome. **Prescribers should consult the SmPC for the complete list of reported side effects. Legal Category:** POM **Marketing Authorisation Numbers:** EU/1/03/256/022, EU/1/03/256/013, EU/1/03/256/017, EU/1/03/256/001, EU/1/03/256/021. **Further information:** available from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24. **HCPs are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.**
Date of revision of PI: June 2018, PI/256/023

Abbreviations: CRP: C-reactive protein.

*21 years refers to clinical trial (since 1997) and post-marketing (since 2003) experience in rheumatoid arthritis.

References: 1. Burmester GR, Mease P, Dijkmans BAC, et al. Adalimumab safety and mortality rates from global clinical trials of six immune-mediated inflammatory diseases. Ann Rheum Dis 2009;68(12):1863–9. **2.** Humira® 40 mg solution for injection in pre-filled pen and syringe, Summary of Product Characteristics, available at www.medicines.ie.

Date of preparation: September 2018.
IREHUR180300(1)

HUMIRA®
adalimumab
destination you™

sobi

Pioneer in Rare Diseases

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients.

We also market a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies.

Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing

We care about patients with rare diseases

www.sobi-uk.co.uk

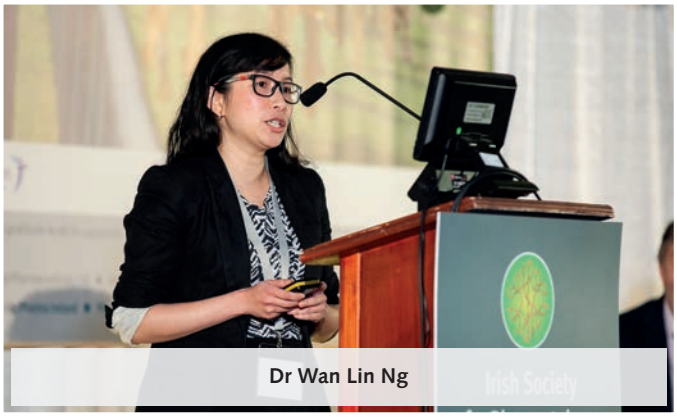
Swedish Orphan Biovitrum Ltd, Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD, UK

NP-2714 Date of preparation: August 2017

ISR Autumn Meeting 2018

Prof Oliver FitzGerald, Prof David Kane, Dr S Harney and Mr Gary Killeen

Prof. Ronan Mullan and Dr Richard Conway



Dr Wan Lin Ng

Prof Oliver FitzGerald, and Dr Gillian Fitzgerald

Dr Afra Al Dhaheri, Dr Dalal Alkhudir and Dr Shamma Al Nokatha

TAPENTADOL

PALEXIA®

DIFFERENT FROM CLASSICAL OPIOIDS*

PALEXIA® SR Tablets are indicated for the management of **severe chronic pain** in adults, which can be adequately managed only with opioid analgesics[1]

PALEXIA® Film Coated Tablets are indicated for the relief of **moderate to severe acute pain** in adults, which can be adequately managed only with opioid analgesics[2]

Grünenthal
Think innovation.
Feel life.®

***Palexia has a unique mode of action. Palexia MOR-NRI.[3]**

PALEXIA® and PALEXIA SR® Prescribing Information
Refer to the Summary of Product Characteristics (SmPC) before prescribing.
Presentation: Palexia: 50 mg (white), 75 mg (pale yellow) and 100 mg (pale pink) film-coated tablets contain 50 mg, 75 mg and 100 mg of tapentadol (as hydrochloride) respectively. Palexia SR: 50 mg (white), 100 mg (pale yellow), 150 mg (pale pink), 200 mg (pale orange) and 250 mg (brownish red) prolonged-release tablets contain 50 mg, 100 mg, 150 mg, 200 mg and 250 mg of tapentadol (as hydrochloride) respectively. **Indication:** Palexia is indicated for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics. Palexia SR is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. **Dosage and method of administration:** Individualise according to severity of pain, the previous treatment experience and the ability to monitor the patient. Swallowed whole with sufficient liquid, with or without food. *Palexia SR:* should not be divided or chewed. The tablet shell may not be completely digested and eliminated / seen in the patient's stool which has no clinical significance as the active substance will have already been absorbed. *Palexia dosage:* Initial dose 50 mg every 4 to 6 hours. On the first day of dosing, an additional dose may be taken 1 hour after the initial dose, if no pain control. The first day's dose should not exceed 700 mg. Maximum maintenance daily dose of up to 600 mg. *Palexia SR dosage:* Initial dose 50 mg twice a day. Switching from other opioids may require higher initial doses. Titrate in increments of 50 mg twice a day every 3 days for adequate pain control. Total daily doses greater than 500 mg not recommended. *Duration of treatment:* Palexia: The possibility of switching to Palexia SR should be considered if longer term treatment is required, and pain relief is achieved with Palexia in the absence of intolerable adverse events. *Discontinuation of treatment:* Taper dose gradually to prevent withdrawal symptoms. *Renal/hepatic impairment:* Not recommended in patients with severe cases. Caution and dose adjustments with moderate hepatic impairment. *Elderly:* May need dose adjustments. *Children below 18 years:* Not recommended. **Contraindications:** Hypersensitivity to ingredients, suspected or having paralytic ileus, acute intoxication with alcohol, hypnotics, centrally acting analgesics or psychotropics. Not for use when mu-opioid receptor agonists are contraindicated (e.g. significant respiratory depression, acute or severe bronchial asthma or hypercapnia). **Special warnings and precautions:** Abuse and addiction potential of Palexia should be considered where there is increased risk of misuse, abuse, addiction or diversion. All patients should be carefully monitored for signs of abuse and addiction. Concomitant use with sedating medicinal products such as benzodiazepines or related substances may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedating medicinal products should be reserved for patients for whom alternative treatment options are not possible. If used concomitantly, reduction of dose of one or both agents should be considered and the duration of the concomitant treatment should be as short as possible. The patients should be followed closely for signs and symptoms of respiratory depression and sedation. It is strongly recommended to inform patients and caregivers to be aware of these symptoms. At high doses or in mu-opioid receptor agonist sensitive patients, dose-related respiratory depression may occur. Caution and monitoring required with impaired respiratory function. Should not use in patients susceptible to intracranial effects of carbon dioxide retention (e.g. increased intracranial pressure, impaired consciousness or coma). Use with caution with head injury, brain tumors, moderate hepatic impairment, biliary tract disease including acute pancreatitis. Not recommended if history of or at risk of seizures. May increase the seizure risk in patients taking other medicinal products that lower the seizure threshold. Not recommended in severe renal or hepatic impairment. Care should be taken when combining with mixed mu-opioid agonists/antagonists (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine). Should not use with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **Interactions:** The concomitant use with sedating medicinal products such as benzodiazepines or other respiratory or CNS depressants (other opioids, antitussives or substitution treatments, barbiturates, antipsychotics, H1-antihistamines, alcohol) increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. When combined therapy with a respiratory or CNS depressant is contemplated, the reduction of dose of one or both agents should be considered and the duration of the concomitant use should be limited. Can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, antipsychotics and other medicinal products that lower the seizure threshold to cause convulsions. There have been reports of serotonin syndrome in a temporal connection with the therapeutic use of tapentadol in combination with serotoninergic medicinal products (such as SSRIs, SNRIs and tricyclic antidepressants). Use with strong inhibitors of uridine diphosphate transferase isoenzymes (involved in glucuronidation) may increase systemic exposure of Palexia/Palexia SR. Caution if concomitant administration of strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort) starts or stops as this may lead to decreased efficacy or risk for adverse events, respectively. Avoid use in patients who have taken monoamine oxidase inhibitors (MAOIs) within the last 14 days, due to cardiovascular events. **Pregnancy and lactation:** Use in pregnancy only if the potential benefit justifies the potential risk to the foetus. Not recommended during and immediately before labour and delivery. Do not use during breast feeding. **Driving and using machines:** May have major effect on ability to drive and use machines, especially at the beginning or change in dosage, in connection with alcohol or tranquilisers. **Undesirable effects:** *Very common (≥1/10):* dizziness, somnolence, headache, nausea. *Palexia only:* vomiting. *Palexia SR only:* constipation. *Common (≥1/100, <1/10):* decreased appetite, anxiety, sleep disorder, tremor, flushing, diarrhoea, dyspepsia, pruritus, hyperhidrosis, rash, asthenia, fatigue, feeling of body temperature change. *Palexia only:* confusional state, hallucination, dry mouth, muscle spasms, constipation, abnormal dreams. *Palexia SR only:* depressed mood, nervousness, restlessness, disturbance in attention, involuntary muscle contractions, dyspnoea, vomiting, mucosal dryness, oedema. *Other important undesirable effects observed in clinical trials and/or postmarketing:* convulsion, impaired gastric emptying *(rare ≥1/10,000, <1/1000). Palexia only:* respiratory depression, dyspnoea *(uncommon ≥1/1000, <1/100),* drug hypersensitivity including angioedema, anaphylaxis and anaphylactic shock, depressed level of consciousness, *(rare ≥1/10,000, <1/1000). Palexia SR only:* drug hypersensitivity, depressed level of consciousness, mental impairment, syncope *(uncommon ≥1/1000, <1/100)*, respiratory depression, angioedema, anaphylaxis and anaphylactic shock, drug dependence *(rare ≥1/10,000, <1/1000).* No evidence of increased risk of suicidal ideation or suicide with Palexia/Palexia SR. Additional information is available on request. **Overdose:** Seek specialist treatment (see SmPC). **Legal classification:** POM, CD (Schedule II). **Marketing Authorisation numbers and pack sizes: Palexia:** 50 mg: PA 2242/12/1, 28 and 56 packs; 75 mg: PA 2242/12/2, 28 and 56 packs; 100 mg: PA 2242/12/3, 28 packs. **Palexia SR:** 50 mg: PA 2242/12/4, 28 and 56 packs; 100 mg: PA 2242/12/5, 56 pack; 150 mg: PA 2242/12/6, 56 pack; 200 mg: PA 2242/12/7, 56 pack and 250 mg: PA 2242/12/8, 56 pack. **Marketing Authorisation Holder:** Grünenthal Pharma Ltd, 4045 Kingswood Road, Citywest Business Park, Citywest, Co. Dublin, Ireland. **M-PLX-IE-01-19-0002. Date of Preparation: January 2019**.

References: 1. Palexia SR Summary of Product Characteristics. **2.** Palexia Film Coated Tablets Summary of Product Characteristics. **3.** Kress, et al. European Journal of Pain, 2010.

Date of Preparation: February 2019. M-PLX-IE-02-19-0005

ISR Autumn Meeting 2018

Attendees at meeting

meto ject®

Metoject® PEN is a pre-filled autoinjector for automatic self-injection of methotrexate (MTX):

- The PEN is ready to use
- The device is designed to ensure a safe application by needle shield and childproof lock system
- It contains a MTX solution of 50 mg/ml and thus the smallest-possible injection volume
- Fast injection in max. 5 seconds

Indicated for

- Rheumatoid arthritis
- Psoriasis
- Psoriatic arthritis

Summary of the most important points

- Ready to use
- Easy to handle, especially for rheumatoid hands
- Safety through automatic needle shield protection and childproof lock
- Reduces injection pain[1]

7.5 mg | **10 mg** | **15 mg** | **20 mg** | **25 mg**

The different doses are colour-coded for an easy identification of the correct dosage.

medac

PRESCRIBING INFORMATION
(Please refer to the Summary of Product Characteristics before prescribing)
Metoject 7.5 mg / 10 mg / 15 mg / 20 mg / 25 mg solution for injection in pre-filled pen.
Therapeutic indications: Metoject is indicated for the treatment of: Active rheumatoid arthritis in adult patients, severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients.
Posology and method of administration: Metoject should only be prescribed by physicians who are familiar with the various characteristics of the medicinal product and its mode of action. Patients must be educated to use the proper injection technique. The first injection of Metoject PEN should be performed under direct medical supervision. Metoject is injected **once weekly.** The patient must be explicitly informed about the fact that Metoject is administered **once a week only.** It is advisable to determine an appropriate fixed day of the week for the injection. Methotrexate elimination is reduced in patients with a third distribution space (ascites, pleural effusions). Such patients require especially careful monitoring for toxicity, and require dose reduction or, in some cases, discontinuation of methotrexate administration (reference section 5.2 and 4.4 of the SPC). *Adults, rheumatoid arthritis:* The recommended initial dose is 7.5 mg of Metoject once weekly, administered subcutaneously. Depending on the individual activity of the disease and tolerability, the dose may be increased gradually by 2.5 mg per week. A weekly dose of 25 mg should in general not be exceeded. Upon achieving the therapeutically desired result, the dose should be reduced gradually to the lowest possible effective maintenance dose. Use in children < 3 years of age is not recommended as insufficient data on efficacy and safety is available for this population (reference section 4.4 of the SPC). *Dosage in patients with psoriasis vulgaris, psoriatic arthritis:* It is recommended that a test dose of 5 – 10 mg should be administered parenterally, one week prior to therapy to detect idiosyncratic adverse reactions. The recommended initial dose is 7.5 mg of methotrexate once weekly, administered subcutaneously. The dose is to be increased gradually but should not, in general, exceed a weekly dose of 25 mg of methotrexate. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. Upon achieving the therapeutically desired result, the dose should be reduced gradually to the lowest possible effective maintenance dose. Maximum weekly dose. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. In a few exceptional cases a higher dose might be clinically justified, but should not exceed a maximum weekly dose of 30 mg of methotrexate as toxicity will markedly increase. Patients with renal impairment: Metoject should be used with caution in patients with impaired renal function (see section 4.3 of SPC for further information). Patients with hepatic impairment: Methotrexate should be administered with great caution, if at all, to patients with significant current or previous liver disease, especially if due to alcohol. If bilirubin is > 5 mg/dl (85.5 µmol/l), methotrexate is contraindicated. *Elderly:* Dose reduction should be considered due to reduced liver and kidney function as well as lower folate reserves. Use in patient with a third distribution space (pleural effusions, ascites): As the half-life of methotrexate can be prolonged to 4 times the normal length in patients who possess a third distribution space dose reduction or, in some cases, discontinuation of methotrexate administration may be required (see section 5.2 and 4.4 of the SPC). Instructions for subcutaneous use: If changing the oral application to parenteral administration a reduction of the dose may be required due to the variable bioavailability of methotrexate after oral administration.
Contraindications: Hypersensitivity to methotrexate or any of the excipients (reference section 6.1 of the SPC); severe liver impairment (reference section 4.2 of the SPC); alcohol abuse; severe renal impairment (creatinine clearance < 30 ml/min reference section 4.2 and section 4.4 of the SPC); pre-existing blood dyscrasias (bone marrow hypoplasia, leukopenia, thrombocytopenia, significant anaemia); serious, acute or chronic infections such as tuberculosis, HIV, other immunodeficiency syndromes; ulcers of the oral cavity and known active gastrointestinal ulcer disease; pregnancy, breast-feeding (reference section 4.6 of the SPC) ; concurrent vaccination with live vaccines.
Special warnings and precautions for use: Patients must be clearly informed that the therapy has to be administered **once a week,** not every day. Patients undergoing therapy should be subject to appropriate supervision so that signs of possible toxic effects or adverse reactions may be detected and evaluated with minimal delay. Therefore treatment with methotrexate should only be initiated and supervised by physicians whose knowledge and experience includes the use of antimetabolite therapy. Because of the possibility of severe or even fatal toxic reactions, the patient should be fully informed by the physician of the risks involved and the recommended safety measures. Recommended examinations and safety measures: Before beginning or reinstituting methotrexate therapy after a rest period: Complete blood count with differential blood count and platelets, liver enzymes, bilirubin, serum albumin, chest x-ray and renal function tests. If clinically indicated, exclude tuberculosis and hepatitis, see section 4.4 of the SPC for further information). During therapy (at least once a month during the first six months and every three months thereafter): An increased monitoring frequency should be considered also when the dose is increased, see section 4.4 of the SPC for further information).
Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".**Interactions with other medicines:** Special care should be taken with Methotrexate and Alcohol, hepatotoxic medicinal products, haematotoxic medicinal products, oral antibiotics, antibiotics, medicinal products with high plasma protein binding, probenecid, weak organic acids, pyrazoles, non-steroidal anti-inflammatory agents, medicinal products with adverse reactions on the bone marrow, medical products which cause folate deficiency, folic acid, other antirheumatic medicinal products, sulphasalazine, mercaptopurine, proton-pump inhibitors, theophylline, caffeine or theophylline-containing beverages. **Fertility, pregnancy and lactation:** Methotrexate is contraindicated during pregnancy and is excreted in breast milk and there is a risk for the infant. Methotrexate can be genotoxic, all women are advised to consult a genetic counselling centre, if possible, already prior to therapy. Men should seek advice about the possibility of sperm preservation before starting therapy. **Effects on ability to drive and use machines:** Central nervous symptoms such as tiredness and dizziness can occur during treatment, Metoject has minor or moderate influence on the ability to drive and use machines. **Undesirable effects**: The following headings are used to organise the undesirable effects in order of frequency: Very common (≥1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥1/10,000 to < 1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data) The most relevant undesirable effects are suppression of the haematopoietic system and gastrointestinal disorders. **Very common:** Gastrointestinal disorders (Stomatitis, dyspepsia, nausea, loss of appetite, **abdominal pain) and Hepatobiliary disorders (Abnormal liver function tests (increased ALAT, ASAT, alkaline phosphatase and bilirubin). Common**: Blood and lymphatic system disorders (Leukopenia, anaemia, thrombopenia), **Uncommon**: Infections and infestations (Pharyngitis), Blood and lymphatic system disorders (Pancytopenia), Metabolism and nutrition disorders (Precipitation of diabetes mellitus), Psychiatric disorders (Depression, Confusion), Nervous System Disorders (dizziness) and Gastrointestinal disorders (Gastrointestinal ulcers and bleeding, enteritis, vomiting, pancreatitis), Hepatobiliary disorders (Cirrhosis, fibrosis and fatty degeneration of the liver, decrease in serum albumin), Skin and subcutaneous tissue disorders (Photosensitisation, loss of hair, increase in rheumatic nodules, skin ulcer, herpes zoster, vasculitis, herpetiform eruptions of the skin, urticarial), Musculoskeletal and connective tissue disorders (Arthralgia, myalgia, osteoporosis), Renal and urinary disorders (Inflammation and ulceration of the urinary bladder, renal impairment, disturbed micturition) and Reproductive system and breast disorders (Inflammation and ulceration of the vagina). **Rare:** Infections and infestations (Infection (ind. reactivation of inactive chronic infection), sepsis, Pneumocystis jirovecii pneumonia, conjunctivitis), Immune system disorders (Allergic reactions, anaphylactic shock, hypogammaglobulinaemia), Psychiatric disorders (Mood alterations), Eye disorders (visual disturbances), Cardiac disorders (Pericarditis, pericardial effusion, pericardial tamponade), VASCULAR DISORDERS (Hypotension, thromboembolic events), Respiratory, thoracic and mediastinal disorders (Pulmonary fibrosis, shortness of breath and bronchial asthma, pleural effusion), Gastrointestinal disorders (Gingivitis), Hepatobiliary disorders (acute hepatitis), Skin and subcutaneous tissue disorders (Increased pigmentation, acne, petechiae, ecchymosis, allergic vasculitis), Musculoskeletal and connective tissue disorders (stress fracture), Renal and urinary disorders (Renal failure, oliguria, anuria, electrolyte disturbances), General disorders and administration site conditions (Fever, wound-healing impairment), See Section 4.8 of the SPC for very rare and unknown undesirable effects.
Overdose: Calcium folinate is the specific antidote for neutralising the toxic undesirable effects of methotrexate.
Legal classification: POM. **Marketing authorisation holder:** Medac Gesellschaft für klinische Spezialpräparate mbH
Theaterstrasse 6, 22880 Wedel, Germany. **Marketing authorisation Number:** PA0623/014/002, PA0623/014/003, PA0623/014/004, PA0623/014/005, PA0623/014/006 **Date of revision of text:** June 2018.

For a copy of the SmPC or further medical information, please contact medical@dccvital.com .
Adverse events should be reported to Fannin Ltd, Pharmacovigilance at +353 (0)86 839 4447 or medical@dccvital.com.
Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 (0) 1 676 4971; Fax:+353 (0)1 676 2517. Website: www.hpra.ie; Email: medsafety@hpra.ie.

Additional information available on request.

References: 1. Hattesohl et al. German Society Rheumatology 2017 doi: 10.3205/17dgrh244.

Fannin

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IE2018/080/00. Date of Preparation: July 2018

ISR Meeting Spring, 2019 Exhibitors

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wishes to express its gratitude to all its sponsors
and in particular to the following 'Major Exhibitors'

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Methofill®

Methotrexate

NEW Self Inject Device from Accord Healthcare

Lower acquisition cost vs Metoject® Pen[1]

ABBREVIATED PRESCRIBING INFORMATION

Please refer to the Summary of Product Characteristics (SmPC) before prescribing **Methofill (Methotrexate) 7.5mg, 10mg, 12.5mg, 15mg, 17.5mg, 20mg, 22.5mg, 25mg, 27.5mg and 30mg, solution for injection in pre-filled injector.** Each pre-filled injector contains 7.5, 10, 12.5, 15, 17.5, 20, 22.5, 25mg, 27.5mg or 30 mg methotrexate.

Indications:

Active rheumatoid arthritis in adults. Polyarthritic forms of severe, active juvenile idiopathic arthritis, when response to nonsteroidal anti-inflammatory drugs (NSAIDs) is inadequate. Severe recalcitrant disabling psoriasis, not adequately responsive to other therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adults. Mild to moderate Crohn's disease alone or in combination with corticosteroids in adults refractory or intolerant to thiopurines.

Dosage and Administration:

Adults with rheumatoid arthritis: Recommended initial dose is 7.5mg of methotrexate once weekly, administered subcutaneously. May be increased gradually by 2.5mg per week. Weekly dose of 25mg should not be exceeded. Doses exceeding 20mg/week are associated with significant increase in toxicity. Response to treatment expected after approximately 4 – 8 weeks. Upon achieving therapeutically desired result, reduce dose gradually to lowest effective maintenance dose. *Children and adolescents below 16 years with polyarthritic forms of juvenile idiopathic arthritis*: Children with body surface area below 0.75m^2 cannot be treated with this product. Recommended dose 10 - 15mg/m. body surface area (BSA)/once weekly by subcutaneous injection. Weekly dosage may be increased to 20mg/m^2 body surface area/once weekly. Increase monitoring frequency if dose increased. Refer patients to rheumatology specialist in the treatment of children/adolescents. Use in children < 3 years of age not recommended. *Psoriasis vulgaris and psoriatic arthritis*: Administer test dose of 5 – 10mg parenterally, one week prior to therapy to detect idiosyncratic adverse reactions. Recommended initial dose 7.5mg once weekly subcutaneously. Increase dose gradually. Do not exceed weekly dose of 25mg. Doses exceeding 20mg per week are associated with significant increase in toxicity. Response to treatment expected after approximately 2 – 6 weeks. Upon achieving therapeutically desired result, reduce dose gradually to lowest effective maintenance dose. Increase dose as necessary but do not exceed maximum recommended weekly dose of 25mg. Exceptionally a higher dose might be clinically justified, but should not exceed a maximum weekly dose of 30mg. *Crohn's Disease*: Induction treatment 25mg/week subcutaneously. Response to treatment expected after approximately 8 to 12 weeks. Maintenance treatment 15mg/week subcutaneously. *Renal impairment*: Use with caution. See SPC for dose adjustments based on creatinine clearance. *Hepatic impairment*: Use with great caution, if at all, in patients with significant current or previous liver disease, especially if due to alcohol. If bilirubin is > _5mg/dl (85.5 µmol/l), methotrexate is contraindicated. *Elderly patients*: Consider dose reduction. *Third distribution space (pleural effusions, ascites)*: Half-life can be prolonged, dose reduction or discontinuation may be required.

Contraindications:

Hypersensitivity. Severe liver impairment. Alcohol abuse. Severe renal impairment (creatinine clearance less than 30 ml/min). Pre-existing blood dyscrasias. Serious, acute or chronic infections Ulcers of oral cavity and known active gastrointestinal ulcer disease. Pregnancy, breast-feeding. Concurrent vaccination with live vaccines.

Warnings and Precautions: Clearly inform patients that therapy should be administered **once a week**, not every day. Supervise patients so that signs of possible toxic effects or adverse reactions are detected and evaluated with minimal delay. Treatment should be initiated and supervised by physicians with knowledge and experience in use of antimetabolite therapy. Possibility of severe/fatal toxic reactions, patients should be fully informed by physician of risks and recommended safety measures. Use in children under 3 is not recommended. *Before beginning or reinstituting treatment*: Complete blood count with differential and platelets, liver enzymes, bilirubin, serum albumin, chest x-ray and renal function tests. If clinically indicated, exclude tuberculosis and hepatitis. *During therapy (at least once a month during the first six months and every three months thereafter)*: Examine mouth and throat for mucosal changes. Complete blood count with differential and platelets. Profound drop in white-cell or platelet counts indicates immediate withdrawal of treatment and appropriate supportive therapy. Advise patients to report signs and symptoms of infection. Monitor patients taking haematotoxic medicinal products (e.g. leflunomide) closely with blood count and platelets. Liver function tests: Do not start treatment if abnormality of liver function tests or liver biopsy present. Stop treatment if abnormalities develop. Treatment may be recommenced if liver function returns to normal. Evaluate need for liver biopsy in psoriasis therapy. Temporary increases in transaminases have been reported. Consider dose reduction or discontinuation in the case of a constant increase in liver-related enzymes. Additional hepatotoxic medicinal products should not be taken unless clearly necessary and consumption of alcohol should be avoided. Monitor liver enzymes closely in patients taking other hepatotoxic products. The same should be taken into account with the simultaneous administration of haematoxic products. Monitor renal function. Where renal function may be compromised (e.g. the elderly), monitor more frequently particularly when concomitant medicinal products affect the elimination of methotrexate, cause kidney damage or can lead to impairment of blood formation. Dehydration may also intensify methotrexate toxicity. Respiratory system: Be alert for symptoms of lung function impairment. Pulmonary effects require quick diagnosis and discontinuation of methotrexate. Pulmonary symptoms (especially dry non-productive cough) or a non-specific pneumonitis occurring during methotrexate therapy may be indicative of a potentially dangerous lesion and require interruption of treatment and careful investigation. Acute or chronic interstitial pneumonitis, often associated with blood eosinophilia may occur and deaths have been reported. This lesion can occur at all dosages. Methotrexate may impair response to vaccination and affect result of immunological tests. Particular caution needed in presence of inactive, chronic infections (e.g. herpes zoster, tuberculosis, hepatitis B or C). Vaccination using live vaccines must not be performed. Malignant lymphomas may occur in which case therapy must be discontinued. Concomitant administration of folate antagonists has been reported to cause acute megaloblastic pancytopenia. Radiation induced dermatitis and sun-burn can reappear (recall-reaction). Psoriatic lesions can exacerbate during UV-irradiation and simultaneous administration of methotrexate. Methotrexate elimination is reduced in patients with a third distribution space (ascites, pleural effusions) requiring careful monitoring for toxicity and dose reduction or discontinuation of methotrexate. Pleural effusions and ascites should be drained prior to initiation of methotrexate. Diarrhoea and ulcerative stomatitis require interruption of therapy. Products containing folic acid, folinic acid or derivatives may decrease effectiveness. Treatment of psoriasis with methotrexate should be restricted to severe recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and only when diagnosis established by biopsy and/or after dermatological consultation. Encephalopathy / Leukoencephalopathy have been reported in oncologic patients. The absence of pregnancy should be confirmed before methotrexate is administered. Contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free". Methotrexate has minor or moderate influence on ability to drive and use machines. **Pregnancy and Lactation:** Contraindicated in pregnancy and lactation. It has been reported that methotrexate treatment could lead to abortion. Women getting pregnant during therapy should receive medical counselling about risk of adverse reactions for the child. Effective contraception (women and men) is required during treatment and for at least 6 months thereafter. Women who wish to become pregnant should consult a genetic counselling centre. Men should seek advice about sperm preservation before starting therapy. **Adverse events include: Adverse events which could be considered serious include:** *Common:* Leukopenia, thrombopenia, pneumonia, interstitial alveolitis/pneumonitis often associated with eosinophilia, *Uncommon*: Pharyngitis, pancytopenia, precipitation of diabetes mellitus, pancreatitis, cirrhosis, fibrosis and fatty degeneration of the liver, renal impairment, gastrointestinal ulcers and bleeding. *Rare*: Pericarditis, pericardial effusion, pericardial tamponade, thromboembolic events, pulmonary fibrosis, acute hepatitis, renal failure, anuria, anaphylactic shock, allergic vasculitis, conjunctivitis, sepsis, hypogammaglobulinaemia. *Very rare*: Acute aseptic meningitis, lymphoma, agranulocytosis, convulsions, paralysis, retinopathy, haematemesis, toxic megacolon, hepatic failure, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome). *Frequency unknown:* Bone marrow suppression, pulmonary toxicity, hepatotoxicity, renal toxicity, neurotoxicity, leukoencephalopathy, encephalopathy. **Other Very Common adverse events:** Stomatitis, dyspepsia, nausea, loss of appetite, abdominal pain, abnormal liver function tests (increased ALAT, ASAT, alkaline phosphatase and bilirubin). **Other Common adverse events**: Anaemia, headache, tiredness, drowsiness, oral ulcers, diarrhoea, exanthema, erythema, pruritus. See SPC for details of other adverse events. **Shelf Life:** 24 months. **Pack size:** 7.5mg/0.15ml; 10mg/0.20ml; 12.5mg/0.25ml;15mg/0.30ml;17.5mg/0.35ml; 20mg/0.40ml; 22.5mg/0.45ml; 25mg/0.50ml; 27.5ml/0.55ml; 30mg/0.60ml. **Marketing Authorisation Holder (MAH):** Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom. **MA Number:** PA 1390/099/002, 003, 004, 005, 006, 007, 008, 009, 010, 011. **Legal Category:** POM. Full prescribing information including the SPC, is available on request from Actavis Ireland Ltd, a subsidiary of Accord Healthcare Ltd, Euro House, Little Island, Co. Cork, Tel: 021-4619040 or www.accord-healthcare.ie/products. Adverse reactions can be reported to Medical Information at Accord Healthcare Ltd. via E-mail: medinfo@accord-healthcare.com or Tel: +44(0)1271385257. **Date of Generation of API:** June 2018 UK&IE/MET/0027/06-18

Adverse events should be reported. Reporting forms and information can be found on the HPRA website (www.hpra.ie), or by e-mailing medsafety@hpra.ie.
Adverse events should also be reported to Medical Information via email: medinfo@accord-healthcare.com or tel: 0044 (0)1271 385257.

Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork, T45 K857. Phone: 021 461 90 40

References: 1. Monthly Index of Medical Specialties (MIMS) www.mims.ie online, July 2018

Date of Preparation: July 2018 UK&IE/MET/0012/04-18(1)

accord
Autoimmune
www.accord-healthcare.ie

ISR Autumn Meeting 2018

Dr John Ryan, Dr Wan Lin Ng, 1st Place Poster and Dr Sinead Harney

Dr Sinead Harney, Dr Yousef Alammari, 1st Place Oral Clinical winner and Dr John Ryan

For the treatment of rheumatoid arthritis in adults

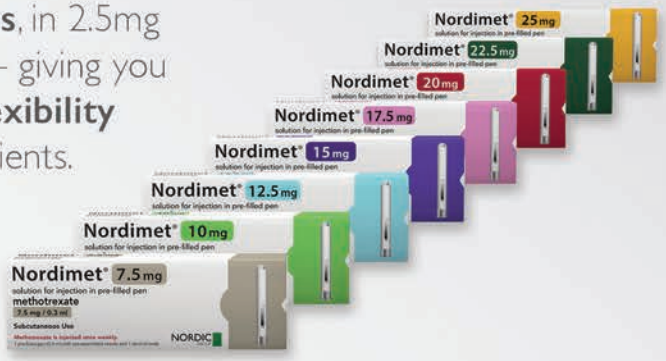
NORDiMET methotrexate

NORDIMET® PEN

THE ONLY METHOTREXATE AUTO-INJECTOR FOR PATIENTS WITH RHEUMATOID ARTHRITIS

Featuring a unique **double click mechanism** at the start and end of each injection, a **compact design** and **NO BUTTON TO PRESS** - designed to give confidence to you and your patients

Available in **8 dose presentations**, in 2.5mg increments from 7.5mg to 25mg – giving you a **wide dosage range** and the **flexibility you need** when treating your patients.



METHOTREXATE AUTO-INJECTOR PEN

Nordimet (methotrexate) Solution for injection in pre-filled pen
Please refer to the Summary of Product Characteristics for full prescribing information. Further information is available on request.
Presentation: Pre-filled pen containing 7.5 mg (in 0.3 ml), 10 mg (in 0.4 ml), 12.5 mg (in 0.5 ml), 15 mg (in 0.6 ml), 17.5 mg (in 0.7 ml), 20 mg (in 0.8 ml), 22.5 mg (in 0.9 ml) and 25 mg (1.0 ml) methotrexate in solution for injection. **Indications:** Active rheumatoid arthritis in adult patients. Polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate. Severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients. **Dosage and administration:** Nordimet should only be prescribed by physicians with experience in the various properties of the medicinal product and its mode of action. Nordimet is injected once weekly, administered subcutaneously. Rheumatoid arthritis: Recommended initial dose is 7.5 mg of methotrexate once weekly. Depending on the individual activity of the disease & patient tolerability, the initial dose may be increased. A weekly dose of 25 mg should in general not be exceeded. Once the desired therapeutic result has been achieved, the dose should be reduced gradually to the lowest possible effective maintenance dose. Polyarthritic forms of severe, active juvenile idiopathic arthritis: The recommended dose is 10-15 mg/m² BSA per week. In therapy-refractory cases the weekly dose may be increased up to 20mg/m² BSA per week. Use in children < 3 years of age is not recommended. Psoriasis vulgaris and psoriatic arthritis: A test dose of 5 - 10 mg subcutaneously administered one week prior to initiation of therapy is recommended. Recommended initial dose 7.5 mg methotrexate once weekly. Dose increased gradually but should not, in general, exceed a weekly dose of 25 mg of methotrexate. Once the desired therapeutic result has been achieved, dose should be reduced gradually to the lowest possible effective maintenance dose. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. Renal impairment, hepatic impairment or elderly patients: Please refer to SmPC. Note: When switching from oral to parenteral use, a reduction in the dose may be required, due to the variable bioavailability of methotrexate after oral administration. **Contraindications:** Hypersensitivity to methotrexate or to any of the excipients. Severe hepatic impairment, if serum bilirubin is > 5 mg/dl (85.5 µmol/l). Alcohol abuse. Severe renal impairment (creatinine clearance < 30 ml/min). Pre-existing blood dyscrasias (e.g. bone marrow hypoplasia, leukopenia, thrombocytopenia or significant anaemia). Immunodeficiency. Serious, acute or chronic infections such as tuberculosis & HIV. Stomatitis. Ulcers of the oral cavity and known active gastrointestinal ulcer disease. Pregnancy. Breast-feeding. Concurrent vaccination with live vaccines. **Special warnings and precautions:** Patients must be clearly advised that the therapy is to be administered once a week, and not every day. Patients receiving therapy should be appropriately monitored. Doses exceeding 20 mg/week can be associated with significant increase in toxicity, especially bone marrow suppression. The possible risks of effects on reproduction, pregnancy loss and congenital malformations should be discussed with male and female patients of childbearing potential. Methotrexate contact with skin and mucosal membranes is to be avoided; in cases of contamination rinse the area with plenty of water. **Interactions:** Consult SPC for detailed information on interactions. **Undesirable effects: See SmPCs for full list of undesirable effects.** Very common: Stomatitis. Dyspepsia. Appetite loss. Abdominal pain. Nausea. Raised liver enzymes. Common: Leukopenia. Anaemia. Thrombopenia. Headache. Tiredness. Drowsiness. Pneumonia. Interstitial alveolitis/pneumonitis. Oral ulcers. Diarrhoea. Exanthema. Erythema. Pruritus. Uncommon: Pharyngitis. Pancytopenia. Precipitation of diabetes mellitus. Depression. Enteritis. Pancreatitis. Gastrointestinal ulceration and bleeding. Cirrhosis, Fibrosis and fatty degeneration of liver. Inflammation and ulceration of bladder. Renal impairment. Rare: Infection. Conjunctivitis. Sepsis. Allergic reactions. Anaphylactic shock. Hypogammaglobulinaemia. Visual disturbances. Pericarditis. Pericardial effusion. Pericardial tamponade. Thromboembolic events. Pulmonary fibrosis. Pneumocystis carinii pneumonia. Shortness of breath and bronchial asthma. Pleural effusion. Acute hepatitis. Renal failure. Anuria. Very rare: Lymphoma. Agranulocytosis. Lymphoproliferative disorders. Severe courses of bone marrow depression. Acute aseptic meningitis. Convulsions. Paralysis. Impaired vision. Retinopathy. Haematemesis. Toxic megacolon. Hepatic failure. Stevens-Johnson syndrome. Toxic epidermal necrolysis. Not known: Eosinophilia. Encephalopathy/Leukoencephalopathy. Pulmonary alveolar haemorrhage. Jaw osteonecrosis (secondary to lymphoproliferative disorders). **Legal classification:** POM. **MA numbers:** EU/1/16/1124/001 – 008. **Further information available from:** Nordic Pharma Ltd, 4045 Kingswood Road, Citywest Business Park, Co Dublin. **Date of Prescribing Information:** June 2018. **Item code:** I/18/NOR/007-00.

Adverse events should be reported.
Reporting forms and information can be found at http://www.hpra.ie
Adverse events should also be reported to Nordic Pharma Ireland: info@nordicpharma.ie
Phone no. +353 (0)1 4004141

Date Of Preparation: January 2019
IE/19/NOR/0007-00

NORDIC PHARMA

ISR Autumn Meeting 2018

Dylan McGagh and Dr Sinead Harney

Dr Leah Rooney and Dr Paul O'Connell

GRAPPA recommended 1st line biologic[1]*

STELARA®

IT'S TIME FOR A DIFFERENT SOLUTION

Proven efficacy across multiple manifestations[1-6]

- ☑ Inhibition of joint damage
- ☑ Lasting improvement in enthesitis and dactylitis
- ☑ Effective in axial involvement
- ☑ Lasting relief of skin symptoms
- ☑ Visible improvements in nail symptoms

…with just 4 maintenance doses per year[7]**

*GRAPPA recommends Stelara® as a 1st line biologic in psoriatic arthritis patients with enthesitis, dactylitis, skin & nail symptoms and axial disease (conditionally)

**Following a loading dose at week 0 and week 4

Stelara® (ustekinumab)

janssen Immunology

PHARMACEUTICAL COMPANIES OF Johnson&Johnson

STELARA® 45 mg and 90 mg solution for injection and 130 mg concentrate for solution for infusion
PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Ustekinumab

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Plaque psoriasis adults: Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA.
Plaque psoriasis paediatrics: Moderate to severe plaque psoriasis in adolescent patients from 12 years of age, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
Psoriatic arthritis: Alone or in combination with methotrexate for treatment of active psoriatic arthritis in adult patients when response to previous non-biological diseasemodifying anti-rheumatic drug (DMARD) therapy has been inadequate.
Crohn's Disease: Treatment of adult patients with moderately to severely active Crohn's disease who had inadequate response with/lost response to/were intolerant to either conventional therapy or TNFα antagonist or have contraindications to such therapies.

DOSAGE & ADMINISTRATION: *Adults*: Under guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis/psoriatic arthritis/Crohn's disease.
Psoriasis or psoriatic arthritis. Subcutaneous (s.c.) injection. Avoid areas with psoriasis. Self-injecting patients or caregivers ensure appropriate training. Physicians are required to follow-up and monitor patients.
Plaque psoriasis, adults & elderly: Patients ≤ 100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients >100 kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients).
Plaque psoriasis paediatrics (12 years and older): Patients <60 kg, 0.75 mg/kg at week 0, followed by 0.75 mg/kg at week 4 then every 12 weeks thereafter. Patients ≥60 - ≤100kg, 45 mg at week 0 followed by 45 mg at week 4, then every 12 weeks. Patients >100 kg, 90mg at week 0, followed by 90mg at week 4, then every 12 weeks.
Psoriatic arthritis, adults & elderly: 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Alternatively, 90 mg may be used in patients with a body weight >100 kg.
Consider discontinuation if no response after 28 weeks.
Crohn's Disease Initial single intravenous infusion dose based on body weight (260 mg or 390 mg or 520 mg) diluted in sodium chloride solution and given over at least one hour. At week 8 after intravenous dose, 90 mg s.c. dose is given; followed by every 12 weeks (or 8 weeks based on clinical judgement). Consider discontinuation if no response at 16 weeks. Immunomodulators and/or corticosteroids may be continued but consider reducing/discontinuing corticosteroids if responding to Stelara. If therapy interrupted, resume s.c. every 8 weeks if safe/effective.
Children: <12 years - Not recommended for psoriasis. ***<18 years*** - Not recommended for psoriatic arthritis and Crohn's disease. ***Renal & Hepatic impairment:*** Not studied.

CONTRAINDICATIONS: Hypersensitivity to product; clinically important, active infection.

SPECIAL WARNINGS & PRECAUTIONS: ***Infections:*** Potential to increase risk of infections and reactivate latent infections. Caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis prior to initiation of STELARA. Consider anti-tuberculosis therapy prior to initiation of STELARA in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, closely monitor and STELARA should not be administered until infection resolves.
Malignancies: Potential to increase risk of malignancy. No studies in patients with history of malignancy or in patients who develop malignancy while receiving STELARA. Monitor all patients, in particular those older than 60, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment for non-melanoma skin cancer. ***Concomitant immunosuppressive therapy:*** Caution, including when changing immunosuppressivebiologic agents.
Hypersensitivity reactions: Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur appropriate therapy should be instituted and STELARA discontinued. **Latex sensitivity:** Needle cover contains natural rubber (latex), may cause allergic reactions. ***Immunotherapy:*** Not known whether STELARA affects allergy immunotherapy.
Serious skin conditions: Exfoliative dermatitis reported following treatment. Discontinue STELARA if drug reaction is suspected.

SIDE EFFECTS: ***Common:*** upper respiratory tract infection, nasopharyngitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, vomiting, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain. ***Other side effects:*** cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema), skin exfoliation, exfoliative dermatitis, lower respiratory tract infection.
Studies show adverse events reported in ≥12 year olds with plaque psoriasis were similar to those seen in previous studies in adults with plaque psoriasis.

Refer to SmPC for other side effects.

FERTILITY: The effect of ustekinumab has not been evaluated.

PREGNANCY: Should be avoided. Women of childbearing potential: Use effective contraception during treatment and for at least 15 weeks post-treatment.

LACTATION: Limited data in humans.

INTERACTIONS: *In vitro*, STELARA had no effect on CYP450 activities. ***Vaccinations:*** Live vaccines should not be given concurrently with STELARA, and should be withheld for at least 15 weeks after last dose of STELARA. STELARA can resume at least 2 weeks after such vaccinations. No data on secondary transmission of infection by live vaccines in patients receiving STELARA. ***Concomitant immunosuppressive therapy:*** Psoriasis: Safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. Psoriatic arthritis: concomitant MTX did not appear to affect STELARA. Crohn's disease: concomitant immunosupressive or corticosteroid therapy did not appear to affect STELARA.

Refer to SmPC for full details of interactions.

LEGAL CATEGORY: Prescription Only Medicine.

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S):

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBERS(S)
45 mg	1 x vial	EU/1/08/494/001
45 mg	1 x 0.5 ml pre-filled syringe	EU/1/08/494/003
90 mg	1 x 1.0 ml pre-filled syringe	EU/1/08/494/004
130 mg	1 x vial	EU/1/08/494/005

MARKETING AUTHORISATION HOLDER: JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.
FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.
Prescribing information last revised: 09/2017

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie Adverse events should also be reported to Janssen-Cilag Limited on +441494 567447 or at dsafety@its.jnj.com.

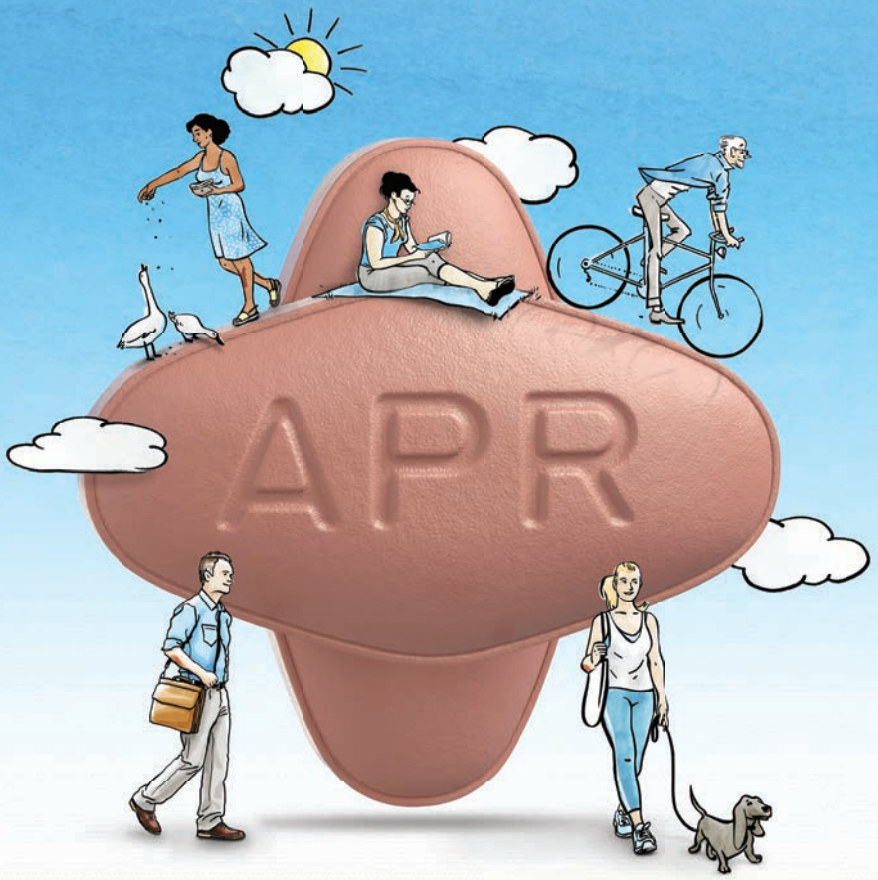
REFERENCES: 1. Coates LC et al. Arthritis Rheumatol 2016;68:1060-1071 **2.** Kavanaugh A et al. Arthritis Care Res (Hoboken) 2015;doi: 10.1002/acr.22645. **3.** Kimball AB et al. J Eur Acad Dermatol Venereol. 2013;27:1535-1545. **4.** Rich P et al. Br J Dermatol. 2014; 170:398-407. **5.** McInnes I et al. Lancet. 2013;382:9894-780-789. **6.** Ritchin C et al. Ann Rheum Dis. 2014;73:990-999. **7.** Stelara® Summary of Product Characteristics, available at www.medicines.ie

PHIR/STE/0718/0005 | Date of Preparation: July 2018

ISR Autumn Meeting 2018

Dr Sinead Harney, Dr Orla Killeen, Dr John Ryan - collecting Dr Charlene Foley's prize

Dr Sarah Wade, Young Investigator Winner, Dr Sinead Harney



Otezla® ▼
(apremilast) 30mg tablets

RESULTS

the way

PATIENTS WANT THEM[1-4]

OTEZLA, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy.[1]

How can OTEZLA help your patients with moderate psoriatic arthritis?

Prescribing Information: OTEZLA® ▼ (apremilast) 10mg, 20mg and 30mg film coated-tablets. Refer to the Summary of Product Characteristics (SPC) before prescribing
Further information is available upon request
Presentation: 10mg, 20mg and 30mg film coated-tablets.
Indications: Psoriatic arthritis: OTEZLA®, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. Psoriasis: OTEZLA® is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA).
Dosage and administration: Treatment with OTEZLA® should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis. The recommended dose of OTEZLA® is 30mg twice daily taken orally, morning and evening, approximately 12 hours apart, with no food restrictions. The film-coated tablets should be swallowed whole. To reduce risk of gastrointestinal symptoms, an initial dose titration is required per the following schedule: Day 1: 10mg in the AM; Day 2: 10mg in the AM and 10 mg in the PM; Day 3: 10mg in the AM and 20mg in the PM; Day 4: 20mg in the AM and 20mg in the PM; Day 5: 20mg in the AM and 30mg in the evening; Day 6 and thereafter: 30mg twice daily. No re-titration is required after initial titration. If patients miss a dose, the next dose should be taken as soon as possible. If it is close to the time for their next dose, the missed dose should not be taken and the next dose should be taken at the regular time. During pivotal trials the greatest improvement was observed within the first 24 weeks of treatment. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment should be reconsidered. The patient's response to treatment should be evaluated on a regular basis.
Special populations: Elderly patients: No dose adjustment is required for this patient population. Patients with renal impairment: No dose adjustment is needed in patients with mild and moderate renal impairment. The dose of OTEZLA® should be reduced to 30mg once daily in patients with severe renal impairment (creatinine clearance of less than 30mL per minute estimated by the Cockcroft-Gault equation). For initial dose titration in this group, it is recommended that OTEZLA® is titrated using only the AM doses and the evening doses be skipped. Patients with hepatic impairment: No dose adjustment is necessary for patients with hepatic impairment Paediatric population: The safety and efficacy of OTEZLA® in children aged 0 to 17 years have not been established. No data is available.
Contraindications: Hypersensitivity to the active substance(s) or to any of the excipients. OTEZLA® is contraindicated in pregnancy. Pregnancy should be excluded before treatment can be initiated.
Special warnings and precautions: Patients with rare hereditary problems of galactose intolerance, lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Severe diarrhoea, nausea, and vomiting associated with the use of Otezla has been reported. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older may be at a higher risk of complications. Discontinuation of treatment may be necessary. OTEZLA® is associated with an increased risk of psychiatric disorders such as insomnia and depression. Instances of suicidal ideation and behaviour, including suicide, have been observed in patients with or without history of depression. The risks and benefits of starting or continuing treatment with OTEZLA® should be carefully assessed if patients report previous or existing psychiatric symptoms or if concomitant treatment with other medicinal products likely to cause psychiatric events is intended. Patients and caregivers should be instructed to notify the prescriber of any changes in behavior or mood and of any suicidal ideation. If patients suffered from new or worsening psychiatric symptoms, or suicidal ideation or suicidal attempt is identified, it is recommended to discontinue treatment with OTEZLA®. OTEZLA® should be dose reduced to 30mg once daily in patients with severe renal impairment. OTEZLA® may cause weight loss. Patients who are underweight at the start of treatment should have their body weight monitored regularly. In the event of unexplained and clinically significant weight loss, these patients should be evaluated by a medical practitioner and discontinuation of treatment should be considered. Women of childbearing potential should use an effective method of contraception to prevent pregnancy during treatment. OTEZLA® should not be used during breast-feeding. No fertility data is available in humans.
Interactions: Co-administration of strong cytochrome P450 3A4 (CYP3A4) enzyme inducer, rifampicin, resulted in a reduction of systemic exposure of OTEZLA®, which may result in a loss of efficacy of OTEZLA®. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with OTEZLA® is not recommended. In clinical studies, OTEZLA® has been administered concomitantly with topical therapy (including corticosteroids, coal tar shampoo and salicylic acid scalp preparations) and UVB phototherapy. There was no clinically meaningful drug-drug interaction between ketoconazole and OTEZLA®. OTEZLA® can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between OTEZLA® and methotrexate in psoriatic arthritis patients. OTEZLA® can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between OTEZLA® and oral contraceptives containing ethinyl estradiol and norgestimate. OTEZLA® can be co-administered with oral contraceptives.
Side effects: The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache, and tension headache. The most common adverse reactions leading to discontinuation during the first 16 weeks of treatment were diarrhoea, and nausea. The overall incidence of serious adverse reactions was low and did not indicate any specific system organ involvement. Very commonly reported adverse events are listed as: diarrhoea* and nausea*. Common adverse events are listed as: bronchitis, upper respiratory tract infection, nasopharyngitis*, decreased appetite*, insomnia, depression, migraine*, tension headache*, headache*, cough, vomiting*, dyspepsia, frequent bowel movements, upper abdominal pain*, gastroesophageal reflux disease, back pain*, fatigue. Prescribers should consult the summary of product characteristics in relation to other side-effects. Hypersensitivity* and risk of triggering suicide* have also been reported. *At least one of these was reported as serious or could be considered serious
Legal category: POM **Marketing authorisation numbers:** EU/1/14/981/001, EU/1/14/981/002 and EU/1/14/981/003. **Marketing authorisation holder:** Celgene Europe BV, Winthontlaan 6 N, 3526KV Utrecht, Netherlands. **For further information contact:** Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom Tel: +44(0)208 831 8300
Date of preparation: July 2018 **Approval code:** UK-OTZ180094a

Please report any suspected adverse reactions directly to the Health Products Regulatory Authority (HPRA) using the online forms at www.hpra.ie or the freepost reporting system

Adverse events should also be reported to Celgene Drug Safety Tel: 1800 936 217 Fax: 1800 936 477

References:
1. OTEZLA (apremilast) 30 mg tablets. Summary of Product Characteristics. Celgene Europe B.V.
2. Lebwohl MG, et al. *J Am Acad Dermatol.* 2014;70(5):871-881.
3. McInnes I, et al. *Ann Rheum Dis.* 2018;77:1588-1589.AB0927.
4. Mease P, et al. *Ann Rheum Dis.* 2018;77:201-202.OP0309.

Date of preparation: March 2019
PM-IE-OTZ-0031

Celgene

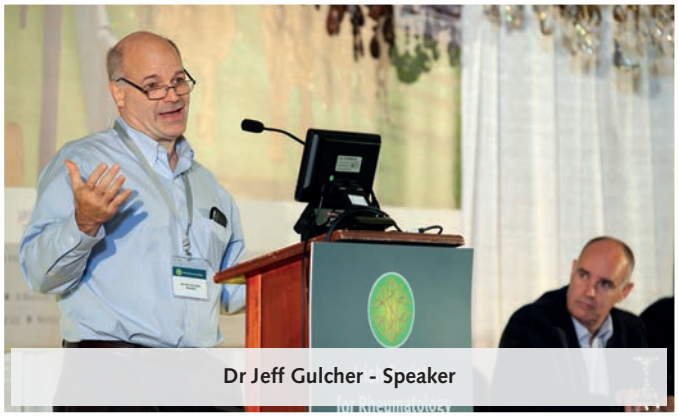
ISR Autumn Meeting 2018


Prof Dirk Elewaut - Speaker


Dr Ian Giles - Speaker


Dr Sandy Fraser


Dr Tim Jones - Speaker


Dr Jeff Gulcher - Speaker

Prof Luke O'Neill - Speaker


Dr Barry O'Shea


Prof Dr Lihi Eder and Peter Nash

100mg Strength
Now Available

Truxima®▼

is rituximab

WHY PAY MORE FOR RITUXIMAB THERAPY?

Truxima®▼ (rituximab) 100mg and 500mg concentrate for solution for infusion Prescribing Information Republic of Ireland. **Please read the Summary of Product Characteristics (SPC) before prescribing. Presentation:** Type I glass vials, with butyl rubber stopper. Each vial contains either 100mg of rituximab in 10mL, or 500mg of rituximab in 50 mL. **Indications and dosage Adult patients:** *Follicular non-Hodgkin's lymphoma (FL) : (i)* as induction treatment in combination with chemotherapy for previously untreated or relapsed refractory patients with stage III-IV FL: 375 mg/m^2 body surface area (BSA) on day 1 of each chemotherapy cycle for up to 8 cycles. *(ii)* as maintenance therapy in previously untreated patients responding to induction therapy: 375 mg/m^2 BSA once every 2 months (starting 2 months after the last dose of induction therapy) until disease progression or for a maximum of 2 years. In relapsed/refractory patients responding to induction therapy: 375 mg/m^2, once every 3 months (starting 3 months after the last dose of induction therapy) until disease progression or for a maximum of 2 years. *(iii)* as monotherapy in patients with stage III-IV FL who are chemo-resistant or are in the second or subsequent relapse after chemotherapy and for retreatment in patients responding to monotherapy: 375 mg/m^2 BSA, administered once weekly for 4 weeks. *Diffuse large B-cell non-Hodgkin's lymphoma (DLBCL):* for treatment of CD20 positive DLBCL in combination with CHOP: 375 mg/m^2 BSA on day 1 of each chemotherapy cycle for 8 cycles. Administer after i.v. infusion of the glucocorticoid component. *Chronic lymphocytic leukaemia (CLL):* in combination with chemotherapy, for previously untreated and relapsed/refractory CLL: 375 mg/m^2 BSA, on day 0 of the first treatment cycle, followed by 500 mg/m^2 BSA on day 1 of subsequent cycles for 6 cycles in total. Prophylactic hydration and uricostatics recommended 48 hours prior to ***Truxima***. Where lymphocyte counts >25x109/L, administration of prednisone/prednisolone 100mg i.v. shortly before ***Truxima*** is recommended. *Rheumatoid arthritis (RA):* in combination with methotrexate (MTX), for adults with severe active RA who have had an inadequate response or intolerance to other DMARDs including one or more TNF inhibitor therapies. 1000mg i.v. infusion followed by a second 1000 mg i.v. infusion two weeks later. Evaluate need for further courses after 24 weeks (see SPC). Premedication with i.v. 100 mg methylprednisolone should be given 30 minutes prior to each infusion. *Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA):* in combination with glucocorticoids, for the induction of remission in adult patients with severe, active GPA (Wegener's) and MPA: 375 mg/m^2 BSA once weekly for 4 weeks. *All indications:* No dose reductions of ***Truxima*** are recommended. Standard dose reductions for any concomitant chemotherapeutic medicinal product should be applied. **Administration:** Give RA, GPA and MPA patients the patient alert card with each infusion. Administer prepared ***Truxima*** as an i.v. infusion, through a dedicated line, with full resuscitation facilities immediately available, under the supervision of an experienced healthcare professional. Do not administer as an i.v. push or bolus. Administer anti-pyretic and an antihistaminic before each infusion. Consider glucocorticoid (GCC) premedication if ***Truxima*** is not given with GCC-containing chemotherapy. Monitor closely for onset or evidence of cytokine release syndrome (CRS). Interrupt infusion immediately if evidence of a severe reaction (e.g. severe dyspnoea, bronchospasm or hypoxia). Evaluate NHL patients for tumour lysis syndrome (TLS). *First infusion:* Recommended initial rate of 50 mg/h for the first 30 minutes, which can then be escalated in increments of 50 mg/h every 30 minutes up to 400 mg/h. *Subsequent infusions:* Recommended initial rate of 100 mg/h and increased by 100 mg/h increments every 30 minutes, up to 400 mg/h. *Alternative faster infusion schedule in RA only (4mg/mL in 250mL infusion volume):* if no serious infusion related reaction (IRR) during first or subsequent infusions at standard rates (above), initiate at 250 mg/h for the first 30 minutes and escalate to 600 mg/h over 90 minutes. Faster infusion not suitable for patients who have clinically significant cardiovascular disease, arrhythmias or previous serious IRR to biologic therapy or rituximab. **Contraindications:** Hypersensitivity to the active substance, murine proteins, or any of the other excipients; active, severe infections; severely immunocompromised patients. Severe heart failure (NYHA class III/IV) or severe, uncontrolled cardiac disease in patients with RA, GPA or MPA. **Precautions and warnings:** To improve the traceability of biological medicinal products, the trade mark and the batch number of the administered product should be recorded in the patient file. *Progressive multifocal leukoencephalopathy (PML):* Very rare cases of fatal PML have been reported. Monitor patients for new or worsening neurological symptoms suggestive of PML and suspend until PML excluded. Permanently discontinue if confirmed. See SPC for further information. *Infusion related reactions (IRRs):* Rituximab is associated with IRRs, including CRS, TLS, anaphylactic and hypersensitivity reactions, including severe reactions with fatal outcome. Severe IRRs are characterised by pulmonary events and may include features of tumour lysis or rapid TLS in addition to reactions such as fever, chills, rigors, hypotension, urticaria and angioedema. Use extreme caution and closely monitor first infusion when treating patients with >25x10^9/L circulating malignant cells or high tumour burden (higher risk of severe CRS). Consider reduced infusion rate or split dosing where lymphocyte counts >25x10^9/L. See SPC for further details on severe IRRs. IRRs of all kinds have been observed in 77% of patients treated with rituximab. Common IRRs are generally reversible with a reduction in rate, or interruption, of rituximab infusion and administration of an antipyretic, an antihistaminic and occasionally, oxygen, i.v. saline or bronchodilators. Temporary or permanent discontinuation may be necessary if severe or if the same adverse events recur a second time. In most cases the infusion can be resumed at a 50% reduction in rate when symptoms have completely resolved. Anaphylaxis and other hypersensitivity reactions have been reported following i.v. administration of proteins to patients. IRRs may also be associated with myocardial infarction, atrial fibrillation, pulmonary oedema and acute reversible thrombocytopenia. Consider withholding antihypertensives for 12 hours prior to infusion due to risk of hypotension. Treat with caution and closely monitor patients with a history of pulmonary insufficiency or pulmonary tumour infiltration. *Cardiac disorders:* Closely monitor patients with a history of cardiac disease and/or cardiac chemotherapy. *Infections:* Patients are at an increased risk of developing infections, including serious infections with fatal outcome. Do not administer if active and/or severe infection present or if severely immunocompromised. Caution in patients with a history of, or susceptibility to recurring/chronic infections. Determining immunoglobulin levels in RA, GPA and MPA before treatment is recommended. Hepatitis B (HBV) reactivation has been reported, including cases with a fatal outcome. HBV screening should be performed before initiation of ***Truxima***. Patients with active hepatitis B disease should not be treated. Patients with positive serology for HBV should consult liver specialists and be monitored and managed to prevent reactivation. *Haematological toxicities:* Caution in patients with neutrophil counts <1.5 x 10^9/L and/or platelet counts <75 x 10^9/L as clinical experience in this population is limited. Perform regular blood counts during ***Truxima*** therapy in all indications, and prior to each course and regularly up to 6-months after cessation of treatment in RA and GPA/MPA. *Immunisations:* Live viral vaccines are not recommended. Response to non-live vaccinations may be reduced. See SPC for further information. *Skin reactions:* Severe skin reactions such as Toxic Epidermal Necrolysis (TEM) and Stevens-Johnson Syndrome (SJS), including fatal outcomes, have been reported - permanently discontinue treatment. *Malignancy:* The possible risk for the development of solid tumours with the use of immunomodulatory drugs cannot be excluded. *Concomitant/sequential use of other DMARDs in RA:* The concomitant use of ***Truxima*** and anti-rheumatic therapies other than those specified for RA is not recommended. Monitor patents for signs of infection if biologic agents and/or DMARDs are used following ***Truxima*** therapy. **Interactions:** Limited data are available (see SPC). Patients with human anti-mouse antibody or human anti-chimeric antibody titres may have allergic or hypersensitivity reactions when treated with other diagnostic or therapeutic monoclonal antibodies. **Fertility, pregnancy and lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 12 months after ***Truxima*** treatment. ***Truxima*** should not be administered during pregnancy. Do not breast-feed in the 12 months following treatment. **Side effects:** *Very common (≥ 1/ 10) and common (≥ 1/100 to <1/10) side effects:* Viral infection, bacterial infection, bronchitis, acute bronchitis, sepsis, pneumonia, febrile infection, herpes zoster, respiratory tract infections, fungal infection, sinusitis, hepatitis B, infections of unknown aetiology, neutropenia/febrile neutropenia, leucopenia, thrombocytopenia, anaemia, pancytopenia, granulocytopenia, infusion related reaction (hypertension, nausea, rash, pyrexia, pruritus, urticaria, throat infection, hot flush, hypotension, rhinitis, rigors, tachycardia, fatigue, oropharyngeal pain, peripheral oedema, erythema), angioedema, hypersensitivity, hyperglycaemia, weight decrease, face oedema, increased LDH, hypocalcaemia, paraesthesia, hypoaesthesia, insomnia, vasodilatation, dizziness, anxiety, agitation, lacrimation disorder, conjunctivitis, tinnitus, ear pain, myocardial infarction/myocardial arrhythmia, atrial fibrillation, cardiac disorder, orthostatic hypotension, bronchospasm, respiratory disease, chest pain, dyspnoea, cough/increased cough, vomiting, diarrhoea, abdominal pain, dysphagia, stomatitis, constipation, dyspepsia, anorexia, throat irritation, alopecia, sweating/night sweats, skin disorder, hypertonia, myalgia, back pain, neck pain, pain, fever, chills, asthenia, headache, tumour pain, flushing, malaise, cold syndrome, shivering, multi-organ failure, decreased IgG levels, urinary tract infection, gastroenteritis, tinea pedis, hypercholesterolemia, migraine, sciatica, depression, oesophageal reflux, mouth ulceration, arthralgia/musculoskeletal pain, muscle spasms, muscle weakness, osteoarthritis, bursitis, decreased IgM levels. Additional side effects in ≥ 5% GPA/MPA patients in clinical trials: Nasopharyngitis, cytokine release syndrome, hyperkalaemia, tremor, acne, epistaxis, nasal congestion, pain in extremities, decreased haemoglobin. *Uncommon (< 1/100) but potentially serious, including fatal, side-effects:* Serious viral infection, Pneumocystis jirovecii, progressive multifocal leukoencephalopathy, reactivation of hepatitis B, infusion related reactions (generalised oedema, bronchospasm, wheezing, laryngeal oedema, angioneurotic oedema, generalised pruritus, anaphylaxis, anaphylactoid reaction), tumour lysis syndrome, cytokine release syndrome, serum sickness, coagulation disorders, aplastic anaemia, haemolytic anaemia, late neutropenia, depression, peripheral neuropathy, cranial neuropathy, severe vision loss, facial nerve palsy, loss of other senses, left ventricular failure, supra-ventricular tachycardia, ventricular tachycardia, angina/angina pectoris, heart failure, atrial flutter, atrial fibrillation, myocardial ischaemia, bradycardia, severe cardiac disorders, vasculitis, leukocytoclastic vasculitis, asthma, bronchiolitis obliterans, hypoxia, respiratory failure, pulmonary infiltrates, interstitial lung disease, gastrointestinal perforation, Steven's-Johnson syndrome, toxic epidermal necrolysis, renal failure. Cases of posterior reversible encephalopathy syndrome (PRES) / reversible posterior leukoencephalopathy syndrome (RPLS) have been reported. Please refer to the SPC for further information and a full list of side effects. **Overdose:** Intravenous doses of up to 5000 mg have been administered in a dose escalation study in CLL patients, which did not identify any safety signals. The infusion should be interrupted immediately and patient monitored closely, if overdose is experienced. **Legal category:** POM. **Presentations:** 100mg (pack of 2 vials) 500mg (1 vial). **Marketing Authorisation numbers:** EU/1/16/1167/001-2.**Marketing Authorisation holder:** Celltrion Healthcare Hungary Kft, 1051 Budapest Bajcsy-Zsilinszky út 12., 4. em. 410.Hungary. For medical information enquiries, please contact info@mundipharma.ie **PI Code:** UK/TRU-17025(1). **Date of Preparation:** September 2017

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See www.hpra.ie for how to report side effects. Distributed in Ireland by: Mundipharma Pharmaceuticals Limited, Millbank House, Arkle Road, Sandyford, Dublin 18, Ireland. Phone +353-1-2063800 www.mundipharma.ie
Date of Item: November 2017. IRE/TRX-17039

Truxima®
Rituximab

mundipharma biosimilars

ISR Autumn Meeting 2018

Karl O'Brien, Anastasia Papavassiliou, and Brenda Colton - Mylan

Dr Gainne Murphy

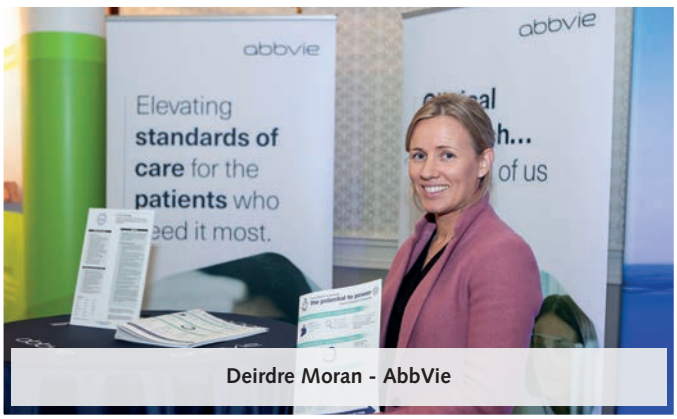
Caroline Eyre and Roisin Joyce-Moss, Pfizer

Dr Karl Quinn, Hannah Convery and Dr Tom O'Dwyer, GMI

Claire Lenihan, Dr Alwin Sebastian and Gerard Walsh, Roche

Conor Doyle, Brian Whately and Kate Barton, Novartis

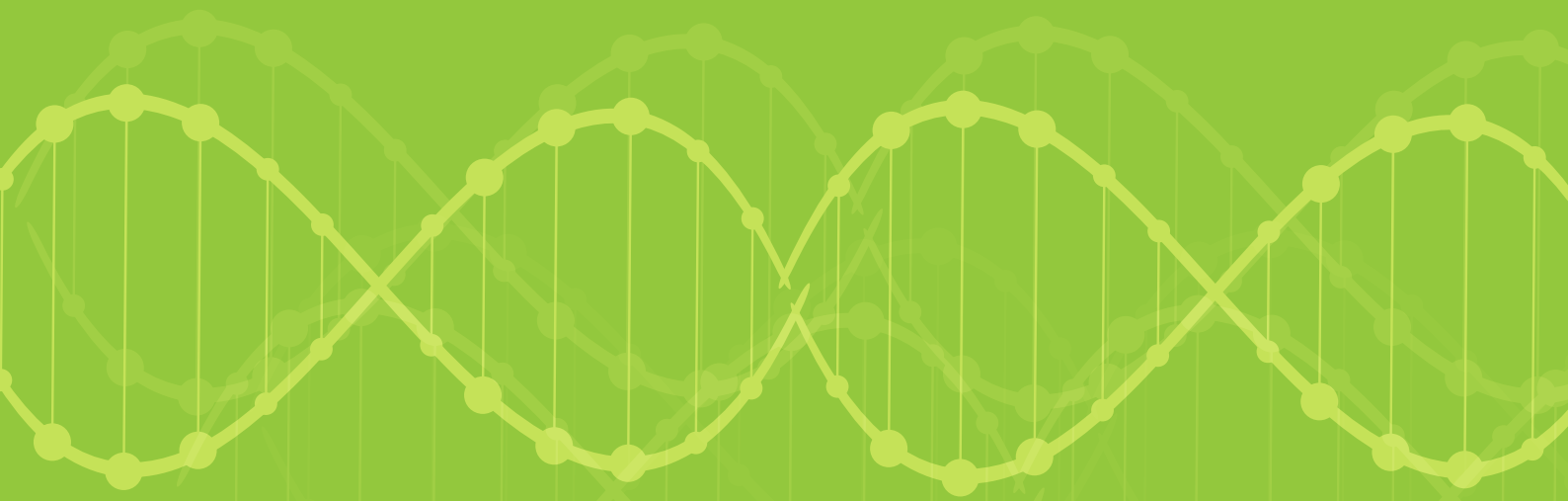
Anna Barrett, Oliver Laurence and Tracy Kivlehan - Accord



Deirdre Moran - AbbVie

Calling all rheumatologists

join our GMI-sponsored research studies



We are expanding our genomic research studies in rheumatology to both public hospitals and private clinics across the island of Ireland.

The study of genomics has tremendous potential to translate to health improvement for patients through diagnostics, disease treatments, prevention and eventually, cures. We're seeking collaborators to partner with us on our journey of scientific discovery.

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Visit our exhibition stand at ISR 2019
Contact Tom O'Dwyer, Clinical Partnerships,
tom.odwyer@genomicsmed.ie

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ISR Autumn Meeting 2018

Nicole O'Keeffe, Norelee Kennedy and Angela Reid

Deyrick Deane, Mark Gorman and Brian McLaughlin - MSD

John O'Sullivan and James Corrigan - A Menarini

Shirley Stone, Edel McGarry and Katrina Walker - UCB

Andrew Browne, AbbVie; Prof. Oliver FitzGerald, Dr Lihi Eder, Speaker; Oliver Kinlough, AbbVie; Dr John Ryan; Karen Walsh, AbbVie

Brian Tonge, Eanna McGowan, Claire Madigan and Kevin Conlon - Janssen

Theresa Higgins, Mary O'Donnell, Mary Maynes and Olive Kelly - Nordic

Sadie Henning, Marise Nyberg, Phil Morris and Marie Brazil, BMS

Hulio™ ▼
(adalimumab)

Hulio® (adalimumab) pre-filled syringe

We support patients!

Hulio® (adalimumab) is a recombinant human monoclonal antibody (mAb) for the treatment of autoimmune diseases, such as rheumatoid arthritis (RA), plaque psoriasis (PP), Crohn's disease and ulcerative colitis. Hulio® (adalimumab) has been developed as a biosimilar of reference adalimumab and is approved by the European Medicines Agency[1]. It is available in two presentations.

The syringe and the autoinjection pen are made of durable plastic rather than glass, preventing accidental breakage and wastage of medicine. Both are also latex-free to prevent allergic reactions and come with narrow 29 Gauge needles for patient comfort.[1]

ABBREVIATED PRESCRIBING INFORMATION:

▼ Hulio (adalimumab) 40 mg solution for injection in pre-filled syringe
▼ Hulio (adalimumab) 40 mg solution for injection in pre-filled pen
▼ Hulio (adalimumab) 40 mg solution for injection
Refer to Summary of Product Characteristics (SmPC) for full information.

Presentation:
Hulio 40 mg solution for injection in pre-filled syringe
Hulio 40 mg solution for injection in pre-filled pen
Hulio 40 mg solution for injection (vial for paediatric use)
Each 0.8 ml single dose pre-filled syringe, pre-filled pen or vial contains 40 mg of adalimumab for subcutaneous injection

Indications:
Rheumatoid arthritis (RA), adults: In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including (MTX). In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces the rate of progression, of joint damage on X-ray and improves physical function, in combination with MTX.
Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above: In combination with MTX for active pJIA with inadequate response to one or more DMARDs. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate.
Enthesitis-related arthritis (ERA), paediatrics 6 years and above: For active ERA with inadequate response to or intolerance to conventional therapy.
Ankylosing spondylitis (AS), adults: For severe active AS with inadequate response to conventional therapy.
Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults: For severe nr-axSpA with objective signs of inflammation (elevated CRP and/or MRI), and an inadequate response to or intolerance to nonsteroidal anti-inflammatory drugs.
Psoriatic arthritis (PsA), adults: For active and progressive PsA with inadequate response to DMARDs. Reduces the rate of progression, of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function.
Psoriasis, adults: For moderate to severe chronic plaque psoriasis in candidates for systemic therapy.
Paediatric Plaque Psoriasis, 4 years and above: For severe chronic plaque psoriasis with inadequate response to or if topical therapy and phototherapies are inappropriate.
Hidradenitis suppurativa (HS), adults and adolescents from 12 years and above: For active moderate to severe HS (acne inversa) with inadequate response to conventional systemic HS therapy.
Crohn's disease (CD), adults: For moderately to severely active CD with no response despite a full and adequate course of, intolerance to or contraindication for a corticosteroid and/or an immunosuppressant therapy.
Paediatric Crohn's disease (CD), 6 years and above: For moderately to severely active CD with inadequate response to, intolerance to or contraindication for conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator.
Ulcerative colitis (UC), adults: For moderately to severely active UC with inadequate response to, intolerance to or contraindication for conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA).
Uveitis, adults: For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.
Paediatric Uveitis, 2 years and above: For chronic non-infectious anterior uveitis with inadequate response to or intolerance to conventional therapy, or in whom conventional therapy is inappropriate.

Dosage and administration: please refer to SmPC for full information.
Hulio treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Hulio is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Hulio (see section 4.4). Patients treated with Hulio should be given the patient alert card.
After proper training in injection technique, patients may self-inject with Hulio if their physician determines that it is appropriate and with medical follow-up as necessary.
During treatment with Hulio, other concomitant therapies (e.g., corticosteroids and/or immunomodulatory agents) should be optimised.
Rheumatoid arthritis (RA), adults: Dosage: 40 mg single dose every other week (EOW). Concomitant MTX should be continued. Glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs, or analgesics can be continued. In monotherapy, patients may require 40 mg every week or 80 mg EOW if they experience a decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose interruption, e.g. before surgery or if serious infection occurs. Reintroduction after 70 days or longer of discontinuation gave same magnitudes of clinical response and similar safety profile as before dose interruption.
Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above: Dosage: 10 kg to < 30 kg 20 mg single dose EOW. If ≥ 30 kg: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.
Enthesitis-related arthritis (ERA), paediatrics 6 years and above: Dosage: 15 kg to < 30 kg: 20 mg single dose EOW. If ≥ 30 kg: 40 mg single dose EOW.
Ankylosing spondylitis (AS), adults: Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.
Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults: Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.
Psoriatic arthritis (PsA), adults: Dosage: 40 mg single dose EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.
Psoriasis, adults: Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time (refer to SmPC).
Paediatric Plaque Psoriasis, 4 to 17 years: Dosage: 15 kg to < 30 kg: 20 mg dose initially followed by 20 mg EOW starting one week after initial dose. If ≥ 30 kg: 40 mg dose initially followed by 40 mg EOW starting one week after initial dose Treatment beyond 16 weeks should be reconsidered if no clinical response in that time.
Hidradenitis suppurativa (HS), adults and adolescents from 12 years and above: Dosage: HS, adults: 160 mg dose initially at Day 1, followed by 80 mg two weeks later at Day 15. Two weeks later (Day 29) continue with a dose of 40 mg every week or 80 mg every other week. HS, from 12 years, weighing at least 30kg: 80 mg dose initially at week 0, followed by 40 mg EOW starting at week 1. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions is recommended to be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no improvement in that time. Reintroduction of treatment after interruption: 40 mg every week or 80 mg EOW. Evaluate periodically the benefit and risk of continued long-term treatment.
Crohn's disease (CD), adults: Dosage: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If decrease in clinical response, can increase dosing frequency to 40 mg every week or 80 mg EOW. Patients with no response by Week 4 may benefit from continued maintenance therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.
Paediatric Crohn's disease (CD), 6 to 17 years: Dosage: < 40 kg: Induction: 40 mg dose at Week 0, followed by 20 mg at Week 2. For a more rapid response: 80 mg at Week 0, followed by 40 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 20 mg dose EOW. If insufficient response, consider an increase in dosing frequency to 20 mg every week. If ≥ 40 kg: Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2; risk of adverse events higher during rapid induction. Maintenance: 40 mg dose EOW. If insufficient response, consider an increase in dosing frequency to 40 mg every week or 80 mg EOW. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time.
Ulcerative colitis (UC), adults: Dosage: Induction: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 40 mg dose EOW. During maintenance, corticosteroids may be tapered in accordance with clinical guidelines. If insufficient response, consider an increase in dosing frequency to 40 mg every week or 80 mg EOW. Treatment beyond 8 weeks should be reconsidered if no clinical response in that time.
Uveitis, adults: Dosage: 80 mg initial dose at Week 0, followed by 40 mg EOW from Week 1. Treatment can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents. Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Hulio. Evaluate on a yearly basis the benefit and risk of continued long-term treatment.
Paediatric Uveitis, 2 years and above: Dosage: < 30 kg: 20 mg dose EOW in combination with MTX. Optional 40 mg loading dose one week prior to start of maintenance therapy. No clinical data in use of loading dose < 6 years of age (see SmPC). If ≥ 30 kg: 40 mg dose EOW in combination with MTX. Optional 80 mg loading dose one week prior to start of maintenance therapy.
Contraindications: Hypersensitivity to the active substance or to any excipients (see SmPC); Active tuberculosis (TB) or other severe infections such as sepsis

References:
1. https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=HULIO&=Refine+results

Legal Category:
Product subject to prescription which may not be renewed. Supply through pharmacies only.

Marketing Authorisation Number:
EU/1/18/1319/002 (pre-filled syringe), EU/1/18/1319/005 (pre-filled pen), EU/1/18/1319/007 (vial)

Marketing Authorisation Holder:
Mylan S.A.S. 117 allée des Parcs, 69800 Saint-Priest, France

Full Prescribing Information available on request from:
Mylan Dublin, Dublin 17. Phone 01 8322250.

Item code: ADA-2018-0059

Date of preparation: February 2019

Hulio® (adalimumab) pre-filled autoinjection pen

Simple two-step injection process. Patients simply remove the cap, and push the device against the skin to trigger the injection.

Durable, latex-free construction.

and opportunistic infections: Moderate to severe heart failure (NYHA class III/IV).

Warnings and precautions: Clearly record the name and batch number of administered product to improve traceability of biological products.

Infections: Patients taking TNF-antagonists are more susceptible to serious infections, especially if impaired lung function. Monitor for infections, including Tuberculosis (TB), before, during and for 4 months after treatment. Do not initiate treatment during an active infection, until infection is controlled. Consider risk/benefit prior to treatment in patients exposed to TB or who have travelled in areas of high risk of TB or endemic mycoses. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis, and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections, including the use of concomitant immunosuppressive medications.

Serious infections: Serious infections, including sepsis, due to bacterial, mycobacterial, invasive fungal, parasitic, viral, or other opportunistic infections such as listeriosis, legionellosis and pneumocystis have been reported.

Other serious infections seen in clinical trials include pneumonia, pyelonephritis, septic arthritis and septicaemia.

Serious infections, including those associated with hospitalisation or death, were reported in patients receiving treatment.

Tuberculosis (TB): Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (i.e. disseminated), were reported. Screen all patients before therapy initiation for active or inactive (latent) TB. Appropriate screening tests (i.e. tuberculin skin test and chest X-ray) should be performed in all patients. If latent TB is suspected, consult physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Hulio. Despite prophylaxis, TB reactivation has occurred on Hulio. If active TB is diagnosed, do not initiate Hulio treatment.

Other opportunistic infections: Opportunistic infections were observed in patients receiving Hulio. Stop treatment in patients with signs and symptoms (i.e. fever, malaise, weight loss, sweats, cough, dyspnoea, and/or pulmonary infiltrates or other serious systemic illness with or without concomitant shock) of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients.

Hepatitis B reactivation: Reactivation of HBV has occurred in chronic carriers (surface antigen positive). Patients should be tested for HBV infection before initiating treatment. HBV carriers should consult a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of treatment. If reactivation occurs, stop treatment and initiate appropriate antiviral and supportive treatment.

Neurological events: Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinuation of treatment should be considered if any of these disorders develop. Neurologic evaluation should be performed in patients with non-infectious intermediate uveitis prior to initiation of treatment and regularly during treatment, to assess for pre-existing or developing central demyelinating disorders.

Allergic reactions: Reports of serious allergic reactions including anaphylaxis were received. For serious allergic or anaphylactic reaction, stop Hulio immediately and initiate appropriate therapy.

Malignancies and lymphoproliferative disorders: A possible risk has been reported of malignancy, including lymphomas and leukaemia, in all patients, including paediatric patients, treated with Tumour Necrosis Factor (TNF) antagonists. Examine all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment, for non-melanoma skin cancer prior to and during treatment; caution in COPD patients, and in patients with increased risk for malignancy due to heavy smoking. Consider the potential risk with the combination of AZA or 6-MP and Hulio (hepatosplenic T-cell lymphoma has occurred). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk of developing dysplasia or colon cancer is unknown. Patients with UC, history of dysplasia or colon carcinoma, to be screened for dysplasia before and during treatment.

Haematologic reactions: Adverse events of the haematologic system reported with Hulio. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias develop while on treatment.

Vaccinations: Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to initiating Hulio treatment.

Congestive heart failure: See contraindications. Caution is advised with mild heart failure (NYHA class I/II). Discontinue treatment if new or worsening symptoms of congestive heart failure.

Autoimmune processes: Autoimmune antibodies may form with Hulio. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA.

Surgery: Consider the long half-life of Hulio for planned surgical procedures. Monitor closely for infections.

Small bowel obstruction: Hulio does not worsen or cause strictures however failure to respond to treatment for Crohn's disease may indicate the presence of fixed fibrotic stricture that may require surgical treatment.

Elderly patients: Serious infections were higher in patients over 65 years of age, some of which had a fatal outcome. Consider risk of infections in these patients.

Interactions with other medicinal products and other forms of interactions: Antibody formation was lower when Hulio was given together with MTX in comparison with use as monotherapy. Combination of Hulio with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended.

Fertility, pregnancy and lactation: Hulio should only be used during pregnancy if clearly needed. Women of childbearing age should consider the use of adequate contraception, and continue its use for at least 5 months after the last treatment. No administration of live vaccines (e.g. BCG) to infants exposed to Hulio in utero for 5 months following mother's last Hulio treatment during pregnancy. Hulio can be used during breast-feeding.

Effects on ability to drive and use machines: Hulio may have a minor influence on the ability to drive and use machines. Vertigo and visual impairment may occur following administration of Hulio (see section 4.8).

Undesirable effects:

Very common ≥ 1/10: Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leukopenia (including neutropenia and agranulocytosis), anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction (including injection site erythema).

Common ≥ 1/100 to < 1/10: Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, cellulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection), urinary tract infections (including pyelonephritis), fungal infections, joint infections, skin cancer excluding melanoma (including basal cell carcinoma and squamous cell carcinoma), benign neoplasm, leucocytosis, thrombocytopenia, hypersensitivity, allergies (including seasonal allergy), hypokalaemia, uric acid increased, blood sodium abnormal, hypocalcaemia, hyperglycaemia, hypophosphatemia, dehydration, mood alterations (including depression), anxiety, insomnia, paraesthesias (including hypoesthesia), migraine, nerve root compression, visual impairment, conjunctivitis, blepharitis, eye swelling, vertigo, tachycardia, hypertension, flushing, haematoma, asthma, dyspnoea, cough, GI haemorrhage, dyspepsia, gastroesophageal reflux disease, sicca syndrome, worsening or new onset of psoriasis (including palmoplantar pustular psoriasis), urticaria, bruising (including purpura), dermatitis (including eczema), onychoclasis, hyperhidrosis, alopecia, pruritus, muscle spasms (including blood creatine phosphokinase increased), renal impairment, haematuria, chest pain, oedema, pyrexia, coagulation and bleeding disorders (including activated partial thromboplastin time prolonged), autoantibody test positive (including double stranded DNA antibody), blood lactate dehydrogenase increased, impaired healing.

Uncommon ≥ 1/1000 to < 1/100: Neurological infections (including viral meningitis), opportunistic infections and tuberculosis (including coccidioidomycosis, histoplasmosis and mycobacterium avium complex infection), bacterial infections, eye infections, diverticulitis, lymphoma, solid organ neoplasm (including breast cancer, lung neoplasm and thyroid neoplasm), melanoma, idiopathic thrombocytopenic purpura, sarcoidosis, vasculitis, cerebrovascular accident, tremor, neuropathy, diplopia, deafness, tinnitus, myocardial infarction, arrhythmia, congestive heart failure, aortic aneurysm, vascular arterial occlusion, thrombophlebitis, pulmonary embolism, interstitial lung disease, chronic obstructive pulmonary disease, pneumonitis, pleural effusion, pancreatitis, dysphagia, face oedema, cholecystitis and cholelithiasis, hepatic steatosis, bilirubin increased, night sweats, scar, rhabdomyolysis, systemic lupus erythematosus, nocturia, erectile dysfunction, inflammation.

Serious, including fatal, adverse reactions have been reported including infections/sepsis, TB, opportunistic infections, allergic reactions (including anaphylaxis), HBV reactivation and malignancies (including leukaemia, lymphoma and hepatosplenic T-cell lymphoma). Serious haematological, neurological and autoimmune reactions have also been reported. These include rare reports of pancytopenia, aplastic anaemia, central and peripheral demyelinating events and reports of lupus, lupus-related conditions and Stevens-Johnson syndrome.

For details of rare and very rarely reported adverse events see SmPC.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie. E-mail: medsafety@hpra.ie.

Adverse events should also be reported to Pharmacovigilance, Mylan, Building 4 – Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9BW, phone no: +44 (0) 800 121 8267,

Email: UKPharmacovigilance@mylan.com.

Mylan

Better Health for a Better World

When life is *too busy for RA*

Given a choice, 53% of RA patients would chose a monthly regime[1*]

GO further with Simponi

With Simponi, approximately 70% of patients remained on treatment after 5 years.[2] ***Make your 1st choice count.***

SIMPONI 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
SIMPONI 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE
(GOLIMUMAB)

ABRIDGED PRODUCT INFORMATION Refer to Summary of Product Characteristics before prescribing **PRESENTATION** Simponi 50 mg solution for injection in pre filled pen Simponi 50 mg solution for injection in pre filled syringe Simponi 100 mg solution for injection in pre filled pen **INDICATIONS** *Rheumatoid Arthritis (RA):* Simponi, in combination with methotrexate (MTX), is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA):* Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS):* Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* Simponi is indicated for the treatment of severe, active *nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. Ulcerative colitis (UC):* Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. *Polyarticular juvenile idiopathic arthritis (pJIA):* Simponi 50mg in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX. **DOSAGE AND ADMINISTRATION** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA, UC or pJIA. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. *RA:* Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. *PsA:* Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. *AS and nr-Axial SpA:* Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. *UC: Patients weighing < 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2. Patients who have an adequate response should receive 50 mg at week 6 and every 4 weeks thereafter. Patients who have an inadequate response may benefit from continuing with 100 mg at week 6 and every 4 weeks thereafter. *Patients weighing ≥ 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12 14 weeks of treatment (after 4 doses). *pJIA:* Simponi 50 mg administered once a month, on the same date each month, for children with a body weight of at least 40 kg. Clinical response is usually achieved within 12 to 14 weeks of treatment (after 3 4 doses). *Missed dose:* If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. *Older patients (≥ 65 years):* no dose adjustment required. *Paediatric patients (<18 years):* For indications other than pJIA, Simponi is not recommended. *Patients with renal and hepatic impairment:* Simponi is not recommended. **CONTRAINDICATIONS** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS AND WARNINGS** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Reminder Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. *Hepatitis B (HBV) reactivation:* Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi *Malignancies and lymphoproliferative disorders:* Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6 mercaptopurine (6–MP). The potential risk with the combination of AZA or 6 MP and Simponi should be carefully considered. A risk for the development for HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma and Merkel cell carcinoma (all TNF-blocking agents including Simponi) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. *Heart Failure:* Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. *Neurological events:* Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. *Surgery:* Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. *Autoimmune processes:* If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. *Haematological reactions:* There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anaemia, and thrombocytopaenia in patients receiving TNF-blockers, including Simponi. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. *Vaccinations/therapeutic infectious agents:* It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. *Allergic reactions:* If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. *Special populations: Older patients (≥ 65 years):* Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. *Paediatric patients (<18 years): Vaccinations:* it is recommended that prior to initiating Simponi therapy, paediatric patients be brought up to date with all immunisations in agreement with current immunisation guidelines. *Excipients:* Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **INTERACTIONS** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **PREGNANCY AND LACTATION** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **SIDE EFFECTS Refer to SmPC for complete information on side effects** *Very Common (≥ 1/10):* upper respiratory tract infection; *Common (≥1/100):* bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, Leukopenia (including neutropenia), anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma, hepatosplenic T-cell lymphoma*, leukopenia, thrombocytopaenia, pancytopaenia, aplastic anaemia, agranulocytosis, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. *Observed with other TNF-blocking agents. *Paediatric population: pJIA:* The safety of golimumab has been studied in a phase III study of 173 pJIA patients from 2 to 17 years of age. The average follow-up was approximately two years. In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies. **PACKAGE QUANTITIES** 1 x 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number** 50 mg Pre-filled Pen EU/1/09/546/001 50 mg Pre-filled Syringe EU/1/09/546/003 100 mg Pre-filled Pen EU/1/09/546/005 **Marketing Authorisation Holder** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands **Date of Revision of Text:** September 2018 Simponi/PI-IRE/09-18 © Merck Sharp & Dohme Ireland (Human Health) Limited 2018. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-2998700) **Date of preparation:** March 2019

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie.
Adverse events should also be reported to MSD (Tel: 01-2998700)

References: 1. Huynh, T.K. et al. Preferences of patients and health professionals for route and frequency of administration of biologic agents in the treatment of rheumatoid arthritis. Patient Preference and Adherence, 2014:8; 93-99. 2. Keystone EC, Genovese MC, Hall S et al. Safety and efficacy of subcutaneous golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: final 5-year results of the GO-FORWARD trial. J Rheumatol. 2016;43:298–306.
*Rheumatoid arthritis patients preferring subcutaneous therapies

MSD
Red Oak North, South County Business Park,
Leopardstown, Dublin D18 X5K7 Ireland

monthly Simponi® golimumab

IE-GOL-00001

Lifetime Achievement Award Dinner
Autumn Meeting 2018

Prof Oliver FitzGerald - Lifetime Achievement Award - Dinner

Prof Oliver FitzGerald

Dr Sinead Harney, ISR President, Dr Paul O'Connell, Prof Oliver FitzGerald

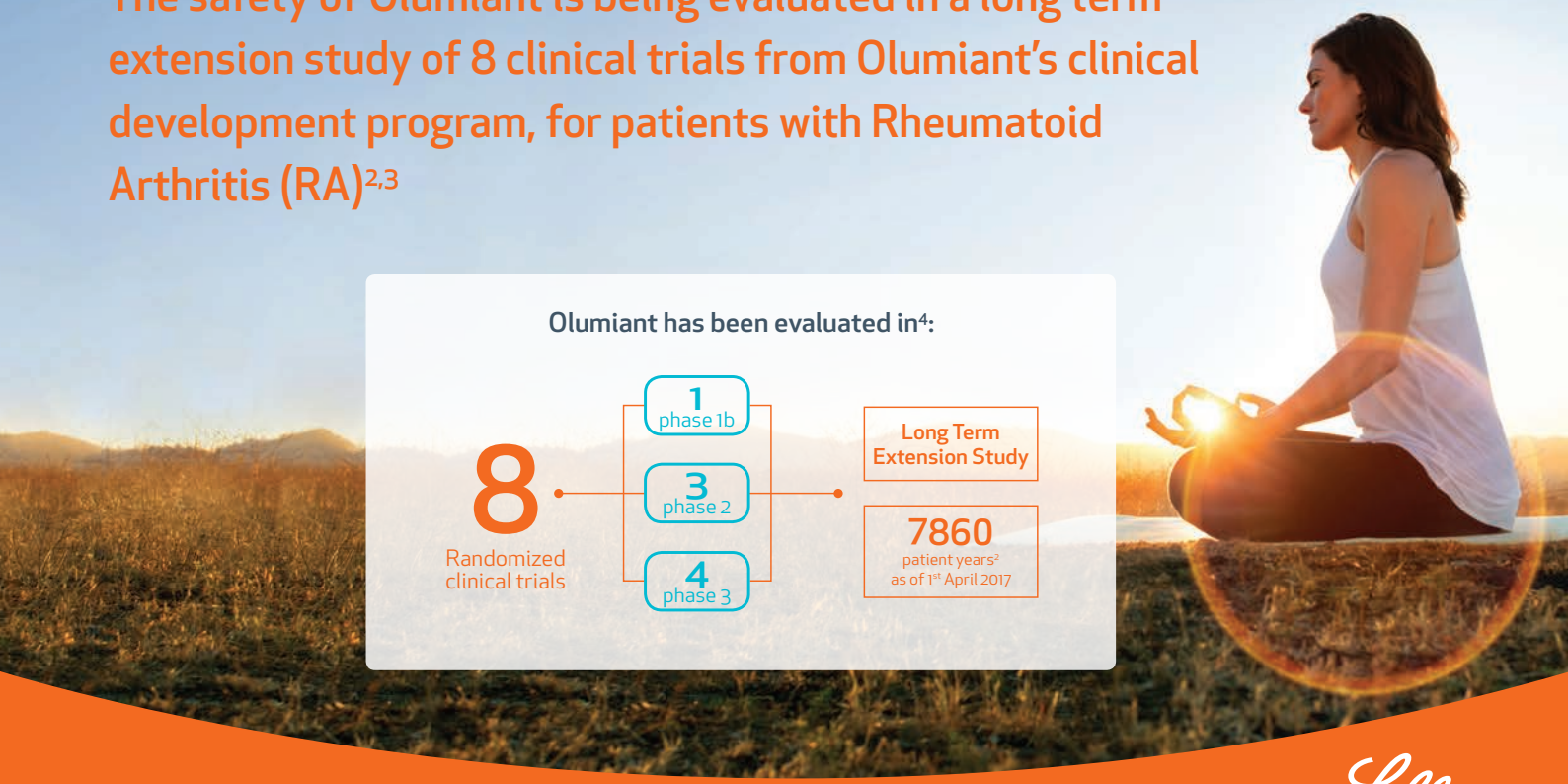
For adult patients with moderate-to-severe active rheumatoid arthritis (RA)

olumiant®
(baricitinib) tablets

REACH BEYOND THE STANDARD

When treating patients who are insufficiently responding, or intolerant, to conventional DMARDs[1]

The safety of Olumiant is being evaluated in a long term extension study of 8 clinical trials from Olumiant's clinical development program, for patients with Rheumatoid Arthritis (RA)[2,3]



Olumiant has been evaluated in[4]:

8 Randomized clinical trials

- **1** phase 1b
- **3** phase 2
- **4** phase 3

→ Long Term Extension Study

7860 patient years[2] as of 1st April 2017

Lilly

Olumiant® (baricitinib) PRESCRIBING INFORMATION

Presentation Olumiant 2 mg film-coated tablet contains 2 mg of baricitinib. Olumiant 2 mg tablet is a light pink, 9.0 x 7.5 mm oblong tablets, debossed with "Lilly" on one side and "2" on the other. Olumiant 4 mg film-coated tablet contains 4 mg of baricitinib. Olumiant 4 mg tablet is a medium pink, 8.5 mm round tablets, debossed with "Lilly" on one side and "4" on the other. **Uses** Olumiant is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate. **Dosage and Administration** Treatment should be initiated by physicians experienced in the diagnosis and treatment of rheumatoid arthritis. Posology The recommended dose of Olumiant is 4 mg once daily. A dose of 2 mg once daily is appropriate for patients such as those aged ≥ 75 years and may be appropriate for patients with a history of chronic or recurrent infections. A dose of 2 mg once daily may also be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. Treatment should not be initiated in patients with an absolute lymphocyte count (ALC) less than 0.5 x 10^9 cells/L, an absolute neutrophil count (ANC) less than 1 x 10^9 cells/L, or who have a haemoglobin value less than 8 g/dL. Treatment may be initiated once values have improved above these limits. *Renal impairment:* The recommended dose is 2 mg once daily in patients with creatinine clearance between 30 and 60 mL/min. Olumiant is not recommended for use in patients with creatinine clearance < 30 mL/min (see the SmPC for full information). *Hepatic impairment:* No dose adjustment is required in patients with mild or moderate hepatic impairment. Olumiant is not recommended for use in patients with severe hepatic impairment (see the SmPC for full information). *Co-administration with OAT3 inhibitors:* The recommended dose is 2 mg once daily in patients taking Organic Anion Transporter 3 (OAT3) inhibitors with a strong inhibition potential, such as probenecid (see the SmPC for full information). No clinical pharmacology study has been conducted with OAT3 inhibitors with less inhibition potential. The prodrug leflunomide rapidly converts to teriflunomide which is a weak OAT3 inhibitor and therefore may lead to an increase in baricitinib exposure. Since dedicated interaction studies have not been conducted, caution should be used when leflunomide or teriflunomide are given concomitantly with baricitinib (see the SmPC for full information on Interaction with other medicinal products and other forms of interaction). *Elderly:* Clinical experience in patients ≥ 75 years is very limited and in these patients a starting dose of 2 mg is appropriate. *Paediatric population:* The safety and efficacy of Olumiant in children and adolescents aged 0 to 18 years have not yet been established. No data are available. Method of administration Oral use: Olumiant is to be taken once daily with or without food and may be taken at any time of the day. **Contra-indications** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC. Pregnancy: Women of childbearing potential have to use effective contraception during and for at least 1 week after treatment. If a patient becomes pregnant while taking Olumiant the parents should be informed of the potential risk to the foetus. **Warnings and Special Precautions** Infections: Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo (see the SmPC for full information). In treatment naïve patients, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. The risks and benefits of treatment with Olumiant should be carefully considered prior to initiating therapy in patients with active, chronic or recurrent infections (see the SmPC for full information). If an infection develops, the patient should be monitored carefully and Olumiant therapy should be temporarily interrupted if the patient is not responding to standard therapy. Olumiant treatment should not be resumed until the infection resolves. *Tuberculosis:* Patients should be screened for tuberculosis (TB) before starting Olumiant therapy. Olumiant should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of Olumiant in patients with previously untreated latent TB. Haematological abnormalities: Absolute Neutrophil Count (ANC) < 1 x 10^9 cells/L, Absolute Lymphocyte Count (ALC) < 0.5 x 10^9 cells/L and haemoglobin < 8 g/ dL were reported in less than 1 % of patients in clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC < 1 x 10^9 cells/L, ALC < 0.5 x 10^9 cells/L or haemoglobin < 8 g/dL observed during routine patient management (see section 4.2 of the SmPC for further information). The risk of lymphocytosis is increased in elderly patients with rheumatoid arthritis. Rare cases of lymphoproliferative disorders have been reported. Viral reactivation: Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies (see the SmPC for full information). Herpes zoster was reported more commonly in patients ≥ 65 years of age who had previously been treated with both biologic and conventional DMARDs. If a patient develops herpes zoster, Olumiant treatment should be temporarily interrupted until the episode resolves. Vaccination: Use with live, attenuated vaccines during, or immediately prior to, Olumiant therapy is not recommended. Prior to initiating Olumiant, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Lipids: Dose dependent increases in blood lipid parameters were reported in patients treated with baricitinib compared to placebo (see the SmPC for full information). Elevations in LDL cholesterol decreased to pre-treatment levels in response to statin therapy. Lipid parameters should be assessed approximately 12 weeks following initiation of Olumiant therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined. Hepatic transaminase elevations: Increases in alanine transaminase (ALT) and aspartate transaminase (AST) to ≥ 5 and ≥ 10 x upper limit of normal (ULN) were reported in less than 1 % of patients in clinical trials. In treatment-naïve patients, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy (see the SmPC for full information). If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, Olumiant should be temporarily interrupted until this diagnosis is excluded. Malignancy: The risk of malignancies including lymphoma is increased in patients with rheumatoid arthritis. Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. The clinical data are insufficient to assess the potential incidence of malignancies following exposure to baricitinib. Venous Thromboembolism: Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. Olumiant should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilisation. If clinical features of DVT/PE occur, Olumiant treatment should be temporarily interrupted and patients should be evaluated promptly, followed by appropriate treatment. Laboratory monitoring: Please refer to the SmPC for laboratory measures and monitoring guidance. Immunosuppressive medicinal products: Combination with biologic DMARDs or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. Data concerning use of baricitinib with potent immunosuppressive medicinal products (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations (see the SmPC for full information). **Interactions** See the SmPC for full information on interaction with immunosuppressive medicinal products, potential for other medicinal products to affect the pharmacokinetics of baricitinib, and potential for baricitinib to affect the pharmacokinetics of other medicinal products. **Fertility, Pregnancy, and Lactation** *Pregnancy:* There are no adequate data from the use of baricitinib in pregnant women. Studies in animals have shown reproductive toxicity (see the SmPC for full information). Baricitinib was teratogenic in rats and rabbits Olumiant is contraindicated during pregnancy. *Breast-feeding:* It is unknown whether baricitinib/metabolites are excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of baricitinib in milk. A decision must be made whether to discontinue breast-feeding or to discontinue Olumiant therapy. *Fertility:* The effect of baricitinib on human fertility has not been evaluated. Studies in animals suggest that treatment with baricitinib has the potential to decrease female fertility while on treatment, but there was no effect on male spermatogenesis. **Effects on ability to drive and use machines** Olumiant has no or negligible influence on the ability to drive and use machines. **Undesirable Effects** *Summary of the safety profile:* The most commonly reported adverse drug reactions occurring in ≥ 2 % of patients treated with Olumiant monotherapy or in combination with conventional synthetic DMARDs were increased LDL cholesterol (33.6 %), upper respiratory tract infections (14.7 %) and nausea (2.8 %). Infections reported with Olumiant treatment included Herpes zoster. *Very common (≥ 1/10):* Upper respiratory tract infection, Hypercholesterolaemia, *Common (≥ 1/100 to < 1/10):* Herpes zoster, Herpes simplex, Gastroenteritis, Urinary tract infections, Pneumonia, Thrombocytosis > 600 x 10^9 cells/L, Nausea, ALT increased ≥ 3 x ULN *Uncommon (≥ 1/1,000 to < 1/100):* Neutropaenia < 1 x 10^9 cells/L, Hypertriglyceridaemia, AST increased ≥ 3 x ULN, Creatine phosphokinase increased > 5 x ULN. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom****: http://www.medicines.org.uk/emc/, or* ***Ireland****: http://www.medicines.ie/.* **Legal Category** POM **Marketing Authorisation Numbers and Holder** EU/1/16/1170/002, EU/1/16/1170/010, EU/1/16/1170/014, Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Cost (UK only)** £805.56 per pack of 28 x 2 mg film-coated tablets, £805.56 per pack of 28 x 4 mg film-coated tablets, £2,416.68 per pack of 84 x 4 mg film-coated tablets. *An Irish price is available on request; please see section below for contact information.* **Date of Preparation or Last Review:** September 2018 **Further information is available from** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: **UK:** + 44-(0) 1256 315000, **Ireland:** + 353-(0) 1 661 4377, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk; www.lilly.ie.

Adverse events and product complaints should be reported. Reporting forms and further information can be found at **UK: www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store, or **Ireland: www.hpra.ie.**

Adverse events and product complaints should also be reported to Lilly: please call **Lilly UK** on **01256 315 000**, or **Lilly Ireland** on **01 664 0446**.

References: 1. Olumiant (baricitinib) tablets. Summary of Product Characteristics. Eli Lilly and Company Ltd. **2.** Genovese MC, et al. Presented at ACR - October 19-24, 2018. Chicago, USA **3.** https://clinicaltrials.gov/ct2/show/NCT01885078 **4.** Genovese MC, Smolen JS, Takeuchi T, et al. Safety profile of baricitinib for the treatment of rheumatoid arthritis up to 5.5 years: an updated integrated safety analysis. In: American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting November 3-8, 2017; San Diego, CA Abstract 511.

ISR Autumn Meeting 2018

ISR Private Practice Meeting

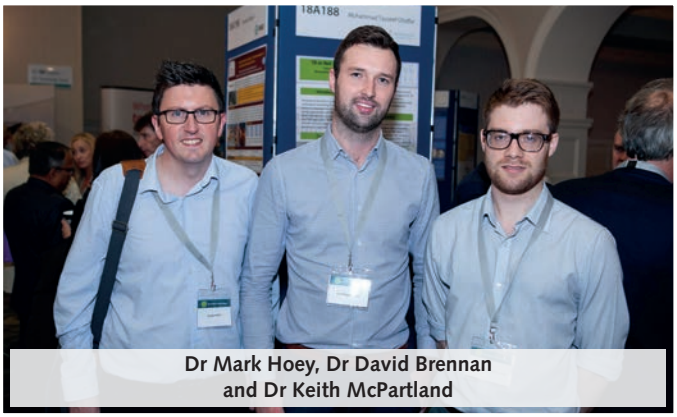
Colm Finlayson - SOBI

John Raftery and Rodger Towey - Amgen

Mary Quinn, Russel Barnes, Pauline Leen and Lynn Grant - Fannin

Declan Connolly, Tom Moloney, Roisin Joyce-Moss, Gillian Dodd - Pfizer

ISR Autumn Meeting 2018



Dr Mark Hoey, Dr David Brennan and Dr Keith McPartland


Dr Evan Fahy and Dr Patrick Mulkerrin


Dr Rachel Flood, Dr Yousef Alammari and Dr Dianna Gheta

Dr Nathaniel Liggett, Dr Gary Wright and Dr Adrian Pendleton


Neill Herbert,Nora Tracey, Kate Barradell and Padraig Culloty - Eli Lilly


Drs Natalie McKee, Donna Torrens and Ursula Laverty

Dr Conor Magee

Dr Daire O'Leary

XELJANZ®▼
(tofacitinib citrate)

MADE IN IRELAND

INDICATED FOR

UC | RA | PsA

RAPID AND SUSTAINED EFFICACY[1-6]

A MARK OF XELJANZ

AN ORAL JAK INHIBITOR FOR THE TREATMENT OF RA, PsA AND UC[7]

XELJANZ®▼ (tofacitinib) Prescribing Information:

Please refer to the Summary of Product Characteristics (SmPC) before prescribing XELJANZ 5 mg or 10 mg film-coated tablets. **Presentation:** Film-coated tablet containing tofacitinib citrate, equivalent to 5 mg or 10 mg tofacitinib. **Indications:** In combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. Can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. In combination with MTX for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease modifying antirheumatic drug (DMARD) therapy. For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. **Dosage:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Tofacitinib is given with or without food. *RA and PsA:* The recommended dose is 5 mg administered orally twice daily. *UC:* The recommended dose is 10 mg given orally twice daily for induction for 8 weeks and 5 mg given twice daily for maintenance. For patients who do not achieve adequate therapeutic benefit by week 8, the induction dose of 10 mg twice daily can be extended for an additional 8 weeks (16 weeks total), followed by 5 mg twice daily for maintenance. Tofacitinib induction therapy should be discontinued in any patient who shows no evidence of therapeutic benefit by week 16. For some patients, such as those who have failed prior tumour necrosis factor (TNF) antagonist therapy, consideration should be given to continuation of the 10 mg twice daily dose for maintenance in order to maintain therapeutic benefit (see SmPC section 5.1). Patients who experience a decrease in response on tofacitinib 5 mg twice daily maintenance therapy may benefit from an increase to tofacitinib 10 mg administered twice daily. It is recommended not to initiate dosing in patients with an absolute lymphocyte count (ALC) less than 0.75×10^9/l, an absolute neutrophil count (ANC) less than 1×10^9 /l or in patients with haemoglobin less than 9 g/dL. *Renal impairment:* No dose adjustment is required in patients with mild or moderate renal impairment. Patients with severe renal impairment the dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal renal function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal renal function is 10 mg twice daily. Patients with severe renal impairment should remain on a reduced dose even after haemodialysis. *Hepatic impairment:* No dose adjustment is required in patients with mild hepatic impairment. Patients with moderate hepatic impairment dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal hepatic function is 5 mg twice daily.Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal hepatic function is 10 mg twice daily. Tofacitinib should not be used in patients with severe hepatic impairment. *Elderly:* No dose adjustment is required in patients aged 65 years and older. Use with caution as increase risk and severity of adverse events. *Drug-drug Interactions:* XELJANZ dose should be reduced to 5 mg once daily in patients receiving potent inhibitors of cytochrome (CYP) P450 3A4 (e.g., ketoconazole). XELJANZ dosage should be reduced to 5 mg once daily in patients receiving one or more concomitant medicinal products that result in both moderate inhibition of CYP3A4 as well as potent inhibition of CYP2C19 (e.g., fluconazole) Coadministration of XELJANZ with potent CYP inducers (e.g., rifampicin) may result in a loss of or reduced clinical response. Coadministration of potent inducers of CYP3A4 with XELJANZ is not recommended. **Contraindications:** Hypersensitivity to any of the ingredients, active tuberculosis (TB), serious infections such as sepsis, or opportunistic infections, severe hepatic impairment, pregnancy and lactation. **Warnings and Precautions:** Tofacitinib should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition for which tofacitinib is indicated. Patients treated with tofacitinib should be given a patient alert card. There was a higher incidence of adverse events for the combination of tofacitinib with MTX versus tofacitinib as monotherapy in RA clinical studies. Tofacitinib should be avoided in combination with biologics and potent immunosuppressants such as azathioprine, 6-mercaptopurine, ciclosporine and tacrolimus. *Infections:* Serious and sometimes fatal infections have been reported in patients administered tofacitinib. Rheumatoid arthritis patients taking corticosteroids may be predisposed to infection. Patients should be closely monitored for infections, with prompt diagnosis and treatment. Treatment should be interrupted if a serious infection develops. Use carefully in elderly or patients predisposed to, or with a history of infection (e.g. diabetes). *Tuberculosis:* Patients should be evaluated for both active and latent TB prior to being treated with tofacitinib, patients who test positive for latent TB should be treated with standard antimycobacterial therapy before administering tofacitinib. *Viral Reactivation:* In clinical studies viral reactivation and cases of herpes zoster have been observed. Screening for viral hepatitis should be performed in accordance with clinical guidelines prior to starting therapy with tofacitinib. The impact on chronic viral hepatitis is not known. *Vaccinations:* Prior to initiating tofacitinib, it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. Live vaccines should not be given concurrently with tofacitinib. *Malignancy:* Lymphomas and other malignancies have been observed in patients treated with tofacitinib. Patients with highly active disease may be at higher risk than the general population. The effect of tofacitinib on the development and course of malignancies is not known. NMSCs have been reported, the risk of NMSC may be higher in patients treated with tofacitinib 10 mg twice daily than in patients treated with 5 mg twice daily. Periodic skin examination is recommended in patients at increased risk. *Interstitial lung disease:* Caution is recommended in patients with a history of chronic lung disease as they may be more prone to infection. Asian patients are known to be at higher risk of ILD caution should be exercised with these patients. *Gastrointestinal perforations:* Tofacitinib should be used with caution in patients who may be at increased risk e.g. diverticulitis or concomitant use of corticosteroids or NSAIDs. *Cardiovascular risk:* Risk factors should be managed as part of usual standard of care. *Hypersensitivity:* Cases of drug hypersensitivity associated with tofacitinib administration have been reported. Allergic reactions included angioedema and urticaria; serious reactions have occurred. If any serious allergic or anaphylactic reaction occurs, tofacitinib should be discontinued immediately . *Laboratory Parameters:* Increased incidence of lymphopenia and neutropenia have been reported and decreases in haemoglobin and should be monitored in accordance with the SmPC. Monitor ANC and haemoglobin at baseline, 4-8 weeks and 3 monthly, ALC at baseline and 3 monthly. Tofacitinib has been associated with increases in lipid parameters maximal effects are observed at 6 weeks. Monitoring should be performed 8 weeks after initiation and managed according to hyperlipidemia guidelines. Increases in liver enzymes greater than 3x ULN were uncommonly reported, use caution when initiating with potential hepatotoxic medicinal products. **Pregnancy & Lactation:** Use of tofacitinib during pregnancy and breast-feeding is contraindicated. **Side Effects:** The most common serious adverse reactions were serious infections; pneumonia, cellulitis, herpes zoster, UTIs, diverticulitis, appendicitis and opportunistic infections. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials were headache, upper respiratory tract infections, nasopharyngitis, diarrhoea, nausea and hypertension. The most commonly reported adverse reactions in patients receiving tofacitinib 10 mg twice daily in the induction studies were headache, nasopharyngitis, nausea, and arthralgia. Commonly reported adverse reactions (≥1/100 to <1/10), were pneumonia, influenza, herpes zoster, urinary tract infection, sinusitis, bronchitis, nasopharyngitis, pharyngitis, anaemia, headache, hypertension, cough, abdominal pain, vomiting, diarrhoea, nausea, gastritis, dyspepsia, rash, arthralgia, pyrexia, oedema peripheral, fatigue, blood creatine phosphokinase increased. Refer to section 4.8 of the SmPC for further information on side effects, including description of selected adverse reactions. **Legal Category:** 51B. **Marketing Authorisation Number:** EU/1/16/1178/003 – 5 mg (56 film-coated tablets); EU/1/16/1178/007 – 10 mg (56 film-coated tablets). **Marketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. ***For queries regarding product availability please contact:*** Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

Last revised: 11/2018.

Ref: XJ 6_0.

RA = Rheumatoid Arthritis. **UC** = Ulcerative Colitis. **PsA** = Psoriatic Arthritis.

1. Mease P, et al. N Engl J Med 2017; 377: 1537–1550. **2.** Gladman D, et al. N Engl J Med 2017; 377: 1525–1536. **3.** Hanauer S et al. Poster presented at: World Congress of Gastroenterology at the American College of Gastroenterology Annual Scientific Meeting; October 13–18, 2017; Orlando, FL, USA. **4.** Sandborn WJ et al. N Engl J Med 2017; 376(18): 1723–1736. **5.** Fleischmann R et al. N Engl J Med 2012; 267: 495–507. **6.** Wollenhaupt J et al. Poster presented at: American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting; November 4–9, 2017; San Diego, USA. **7.** XELJANZ Summary of Product Characteristics.

Pfizer

PP-XEL-IRL-0425
Date of preparation: February 2019

RoACTEMRA®
tocilizumab

Roche

10 YEARS TREATING PATIENTS

INDICATED FOR[1] RA | GCA | pJIA | sJIA

RA: Rheumatoid Arthritis; GCA: Giant Cell Arteritis; pJIA: Juvenile idiopathic polyarthritis; sJIA: Systemic juvenile idiopathic arthritis

ABRIDGED PRESCRIBING INFORMATION (API). For full prescribing information, refer to the Summary of Product Characteristics [SmPC]. RoActemra* (tocilizumab) 162mg solution for injection in pre-filled syringe (RoActemra SC PFS). RoActemra* (tocilizumab) 162mg solution for injection in pre-filled pen (RoActemra SC PFP). RoActemra* (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV). Indications: RoActemra SC PFS & PFP: In combination with methotrexate (MTX) for (i) the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX (ii) the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. RoActemra SC is also indicated for the treatment of Giant Cell Arteritis (GCA) in adults. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients ≥ 2 years of age, who responded inadequately to previous therapy with NSAIDs and systemic corticosteroids, (iv) juvenile idiopathic polyarthritis (pJIA) (rheumatoid factor positive or negative and extended oligoarthritis) in patients ≥ 2 years of age, who responded inadequately to previous therapy with MTX. RoActemra IV and RoActemra SC (in RA) can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. RoActemra IV/SC has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX for the treatment of adult RA patients. RoActemra is also indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, GCA, sJIA, pJIA or CRS and all patients should be given the Patient Alert Card. Assess suitability of patient for subcutaneous home use and instruct patient to inform HCP before administering the next dose if they experience symptoms of an allergic reaction. Patients should be instructed to seek immediate medical attention if they develop symptoms of serious allergic reactions. The first injection should be performed under the supervision of a qualified health care professional. Limited data available regarding switching patients from RoActemra IV to RoActemra SC. Patients switching from RoActemra IV to RoActemra SC should administer their first subcutaneous dose at the time of the next scheduled IV dose under the supervision of a qualified HCP. The first injection should be performed under the supervision of a qualified health care professional. A patient can self-inject RoActemra only if the physician determines that it is appropriate and the patient agrees to medical follow-up as necessary and has been trained in proper injection technique. **RA:** *RoActemra IV:* 8mg/kg body weight diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients >100kg, doses >800mg per infusion are not recommended. No data on doses above 1.2g. *RoActemra SC PFS & PFP:* Not intended for IV administration. RoActemra SC PFS is administered with a single-use PFS+NSD. RA - 162mg subcutaneous once every week, irrespective of weight. Patients may self-inject after training. Alternate injection site frequently (see SmPC for further details). Do not shake the syringe or pen. **GCA (RoActemra SC PFS & PFP only):** 162mg subcutaneous once every week in combination with a tapering course of glucocorticoids. RoActemra can be used alone following discontinuation of glucocorticoids. RoActemra monotherapy should not be used for the treatment of acute relapses as efficacy is not established in this setting. Based upon the chronic nature of GCA, treatment beyond 52 weeks should be guided by disease activity, physician discretion, and patient choice. Glucocorticoids should be given according to medical judgement and practice guidelines. **CRS (RoActemra IV):** in patients weighing ≥ 30kg, 8mg/kg diluted to a final volume of 100ml or, 12mg/kg diluted to final volume of 50ml for patients < 30kg, given by IV infusion over 1 hour. Can be given alone or in combination with corticosteroids. If no clinical improvement after the first dose, up to an additional 3 doses may be administered. The interval between consecutive doses should be at least 8 hours. Doses exceeding 800 mg per infusion are not recommended in CRS patients. Patients with severe or life-threatening CRS frequently have cytopenias or elevated ALT or AST due to the underlying malignancy, preceding lymphodepleting chemotherapy or the CRS. **sJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients ≥2 years, 8mg/kg diluted to final volume of 100ml for patients ≥ 30kg, or, 12mg/kg diluted to final volume of 50ml for patients < 30kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients <2 years of age - no data. Patients ≥2 years of age, 8mg/kg diluted to final volume of 100ml for patients ≥ 30 kg or 10 mg/kg diluted to final volume of 50ml for patients <30kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. A change in dose for sJIA/pJIA patients should only be based on a consistent change in the patient's body weight over time. *Dose adjustments:* For raised liver enzymes, modify concomitant DMARDs (RA) or immunomodulatory agents (GCA) if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). In patients not previously treated with RoActemra, initiation is not recommended in patients with an absolute neutrophil count (ANC) below 2 x 10^9/L. Refer to SmPC for information regarding missed subcutaneous doses. *Special Populations:* No data available for RoActemra SC in patients <18 years of age. Closely monitor renal function in patients with severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients >65 years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Special Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Do not initiate treatment in patients with active infections. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Vigilance for the timely detection of serious infection is recommended - signs and symptoms of acute inflammation may be lessened, due to suppression of the acute phase reaction. Consider effects of RoActemra on C-reactive protein (CRP), neutrophils and signs and symptoms of infection when evaluating a patient for a potential infection. Instruct patients and parents/guardians of sJIA and pJIA patients to contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Advise patients to seek medical attention if sign/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Promptly evaluate patients presenting with symptoms potentially indicative of complicated diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment even if they have received premedication with steroids and anti-histamines. Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction during treatment with RoActemra. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, immediately stop administration and permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. In clinical trials, transient or intermittent mild-moderate elevations of hepatic transaminases reported commonly with RoActemra treatment, without progression to hepatic injury. An increased frequency of these elevations was observed when potentially hepatotoxic drugs (e.g. MTX) were used in combination with RoActemra. When clinically indicated, consider other liver function tests including bilirubin. Not recommended in patients with baseline ALT or AST > 5 x ULN; caution in patients with ALT or AST > 1.5 x ULN (see SmPC for frequency of monitoring and dose modifications/interruptions). Decreases in neutrophil and platelet counts have occurred following treatment with RoActemra 8 mg/kg in combination with MTX. Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC < 0.5 x 10^9/L or platelet count < 50 x 10^3/µL. Do not initiate RoActemra treatment where ANC is below 2 x 10^9/L. Caution in patients with low platelet count; monitor neutrophils and platelets in RA, GCA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; assess every 4 to 8 weeks; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). RA patients have an increased risk for cardiovascular disorders - manage risk factors (e.g. hypertension, hyperlipidaemia) as part of usual standard of care. Not recommended for use with other biological agents. RoActemra (for IV use) contains 1.17 mmol (or 26.55 mg) sodium per maximum dose of 1200 mg – to be considered by patients on a controlled sodium diet. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients – RoActemra not studied in patients during an active MAS episode. Trade name and batch number should be clearly recorded in patient file to improve traceability of biological medicines. **Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or 2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions). **Fertility, Pregnancy & Lactation:** Women of childbearing potential (WCBP) must use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. An animal study showed increased risk of spontaneous abortion/embryo-foetal death at high dose. The potential risk for humans is unknown. RoActemra should not be used during pregnancy unless clearly necessary. It is unknown whether RoActemra is excreted in human breast milk. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Non-clinical data available suggests that RoActemra has no effect on fertility. Refer to SmPC. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV:** *RA:* The most commonly reported ADRs (occurring in ≥ 5% of patients treated with tocilizumab monotherapy or in combination with DMARDs) were upper respiratory tract infections, nasopharyngitis, headache, hypertension and increased ALT. The most serious ADRs were serious infections, complications of diverticulitis, and hypersensitivity reactions. ADRs occurring in RA trials: *Very Common (≥1/10):* upper respiratory tract infections, hypercholesterolaemia (including elevations collected as part of routing laboratory monitoring). *Common (≥1/100 - <1/10):* cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased (including elevations collected as part of routing laboratory monitoring), hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. *Uncommon (≥1/1000 - <1/100):* diverticulitis, stomatitis, gastric ulcer, hypertriglyceridaemia, nephrolithiasis, hypothyroidism. *sJIA:* ADRs were similar to those seen in RA patients. sJIA patients experienced a higher frequency of nasopharyngitis, decrease in neutrophil counts, hepatic transaminases increased, and diarrhoea. *Very Common (≥ 1/10):* upper respiratory tract infections, nasopharyngitis, decrease in neutrophil count. *Common (≥1/100 - <1/10):* diarrhoea, infusion related reactions, headache, platelet count decreased, cholesterol increased. *pJIA:* ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. *Very Common (≥ 1/10):* upper respiratory tract infections, nasopharyngitis, headache. *Common (≥1/100 - <1/10):* nausea, diarrhoea, infusion related reactions, hepatic transaminases increased, decrease in neutrophil count. *Uncommon (≥1/1000 - <1/100):* platelet count decreased, cholesterol increased. *CRS:* The safety of RoActemra in CRS has been evaluated in a retrospective analysis of data from clinical trials, where 51 patients were treated with intravenous RoActemra 8 mg/kg (12 mg/kg for patients less than 30 kg) with or without additional high-dose corticosteroids for severe or life-threatening CAR T-cell-induced CRS. A median of 1 dose of RoActemra (range, 1-4 doses) was administered. **RoActemra SC PFS & PFP:** RA - The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. GCA - The safety of subcutaneous RoActemra has been studied in one Phase III study (WA28119) with 251 GCA patients. The overall safety profile observed in the RoActemra treatment groups was consistent with the known safety profile of RoActemra. 6% of patients reported an ADR occurring at the site of a subcutaneous injection. Injection site reactions are reported as very common (≥ 1/10) with the use of the PFS and common (≥1/100 - <1/10) with the use of the PFP. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. *See SmPC section 4.8 for instructions on the reporting of suspected adverse reactions.* **Legal Category:** Subject to medical prescription which may not be renewed (A). **Presentations & Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/001); 200mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled pen (EU/1/08/492/009). **Marketing Authorisation Holder:** Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of API Preparation:** September 2018. *API (IE/RACTE/0816/0019(5)) based on the RoActemra 162 mg solution for injection in PFS and PFP SmPCs dated 12-Apr-2018 and RoActemra 20 mg/ml concentrate for solution for infusion SmPC dated 23-Aug-2018.* **References: 1.** RoACTEMRA Summary of Product Characteristics 15th January 2019. Available at www.medicines.ie. **Date of item:** February 2019. IE/RACTE/0219/0006