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Irish Society
for Rheumatology

Spring Meeting 2017



7 April 2017
Strand Hotel, Limerick



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PHARMACEUTICAL COMPANIES
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NOW AVAILABLE IN
SUBCUTANEOUS
(SC)

THINK RoACTEMRA¹

IN DMARD-IR AND TNF-IR RA PATIENTS,
WHEN COMBINATION WITH MTX IS NOT AN OPTION

ABRIDGED PRESCRIBING INFORMATION (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). **RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC).** **Indications:** **RoActemra SC:** 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 adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. **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/SC 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. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. Assess suitability of patient for subcutaneous home use and instruct patient to inform HCP if they experience symptoms of an allergic reaction before administering the next dose. Limited data available regarding switching patients from RoActemra IV to RoActemra SC. **RA: RoActemra IV:** 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients >100 kg, doses >800 mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Alternate injection site frequently. **sJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients ≥ 2 years, 8mg/kg diluted to final volume of 100ml for patients ≥ 30 kg or 12mg/kg diluted to final volume of 50ml for patients <30 kg 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 <30 kg 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. **Dose adjustments:** For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or 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 $2 \times 10^9/l$. **Special Populations:** No data available for RoActemra SC in patients <18 years of age. Closely monitor renal function in patients with moderate to 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. **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, associated with 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. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Patients to seek medical attention if signs/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. 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 $> 5 \times$ ULN; caution in patients with ALT or AST $> 1.5 \times$ 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 $< 0.5 \times 10^9/l$ or platelet count $< 50 \times 10^9/l$. Do not initiate RoActemra treatment where ANC is below $2 \times 10^9/l$. Caution in patients with low platelet count; monitor neutrophils and platelets in RA, 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 should be clearly recorded in patient file to improve traceability of biological medicines. **Drug 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 must use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-fetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. No lactation data in humans. 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. 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:** ADRs occurring in RoActemra trials: **Very Common ($\geq 1/10$):** upper respiratory tract infections, hypercholesterolaemia. **Common ($\geq 1/100$ - $<1/10$):** 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, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. **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 ($\geq 1/10$):** upper respiratory tract infections, nasopharyngitis, decrease in neutrophil count. **Common ($\geq 1/100$ - $<1/10$):** 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 ($\geq 1/10$):** upper respiratory tract infections, nasopharyngitis, headache. **Common ($\geq 1/100$ - $<1/10$):** nausea, diarrhoea, infusion related reactions, hepatic transaminases increased, decrease in neutrophil count. **RoActemra SC:** 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. **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). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. 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 Preparation:** August 2016. **Reference:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. Int. J. Clin. Rheumatol. (2012) 7(1): 9-19. **Date of item:** September 2016. IE/RAC/TE/0916/0020



RoACTEMRA®
tocilizumab



Welcome Message from the ISR President Dr Sandy Fraser



Dear Colleagues and Friends

I have great pleasure in welcoming you all to the Strand Hotel Limerick for the 2017 ISR Spring Meeting. I am grateful to all of you who have taken time out of your busy schedules to travel to Limerick for the meeting and I hope you all find it interesting. As a Dubliner now living in the wild west I can honestly say that Limerick and the environs are full of wonderful and interesting things to do and places to see. I hope you get a bit of weather while you are visiting which always helps. May I take this opportunity to suggest if you have a moment King John's Castle is well worth a visit. Steeped in history common to both Ireland, England and Vikings it never fails to be a fascinating port of call.

My colleagues Joe Devlin and John Paul Doran and I have I hope you will agree put together an interesting academic programme. It is a great pleasure to have finally managed to persuade Professor Maya Buch to escape her busy schedule and visit Ireland. Maya trained and practiced with Joe and I in Leeds and many other Irish Rheumatologists who have trodden the well worn path to Yorkshire. Maya promises to "Navigate the Biologics Landscape" for us which will be most useful. Our own Professor Gerry Wilson will update us on the progress of our RA Biologics Registry (RABRI) and following coffee Noirin Lennox, Health Psychologist and Helen Rooney, Chartered Physiotherapist will talk about the highly successful programme regarding pain acceptance and commitment we have been running in University Hospitals Limerick for the past few years.

Professor Austin Stack is our Professor of Medicine at the University of Limerick Medical School and a world leader in the study of hyperuricaemia and its potential role as an independent risk factor for cardiovascular and renal diseases beyond its role in gout. Since musculoskeletal radiologist Dr Philip Hodnett took up his post in UHL he has been a major asset to all of us dealing with MSK diseases. A UCD graduate, he completed a Fellowship in diagnostic MSK radiology in NYU Hospitals, New York before returning to Ireland. Widely published he has a specific interest in the Seronegative Spondyloarthropathies.

Finally Professor Howard Amital travels from Tel Aviv to speak about a new era in RA therapy and where JAK inhibitors will fit into current treatment pathways.

Enjoy the meeting, enjoy Limerick and thanks again to our colleagues in the pharmaceutical industry who continue to support the ISR and many individual units around the country. Please take time to visit the industry stands.

Regards

Dr Sandy Fraser,
ISR President



Transforming lives¹

15 years
of clinical
trials
and real world
experience¹

1st approved
anti-TNF
in RA¹⁻⁷

More than
400
trials¹⁸

5 Over
million
patient-years
of collective
clinical experience¹¹

More than
6400
publications¹⁹

1 Over
million
patients
treated¹⁰

of partnership and experience
over
15
years



ABBREVIATED PRESCRIBING INFORMATION

Enbrel[®] etanercept

Before prescribing Enbrel[®] please refer to full Summary of Product Characteristics (SmPC). **Presentation:** Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC[®]): Enbrel 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. Non-radiographic axial spondyloarthritis (nr-axSpA). Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). Children aged 6-17 years: Juvenile idiopathic arthritis (JIA). Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesitis-related arthritis from the age of 12 years when inadequate response to, or intolerant of conventional therapy. Children aged 6-17 years: Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** By subcutaneous injection. Adults: RA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS, nr-axSpA and PsA – 25 mg twice weekly or 50 mg once weekly. Children aged 2-17 years: JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. Children aged 6-17 years: Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure (CHF). There have been rare (< 0.1%) reports of new onset CHF, including CHF in patients without known preexisting cardiovascular disease, including patients under 50 years of age. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients previously infected with hepatitis B and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy ≤ 18 years of age) in the post marketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have been reported very infrequently in patients treated with Enbrel. Periodic skin

examination is recommended for all patients, particularly those with risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and lifethreatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, heart failure, autoimmune hepatitis, Steven Johnson's syndrome, anaphylaxis, and very rare reports of: toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type I diabetes mellitus and soft tissue and post-operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. See section 4.8 of the SmPC for how to report adverse reactions. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC): Each carton contains 4 pre-filled pens containing 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **Legal Category:** S1A.

European Marketing Authorisation Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. **For full prescribing information see the Summary of Product Characteristics. 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. **API Reference Number:** EN 9_0 Pfilet number: 2015-0011787, 2015-0011936, 2016-0015782. **Date of Prescribing Information:** April 2016.

† Across all indications.

References: 1. Scott LJ. Drugs. 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. 3. Humira Summary of Product Characteristics. 4. Remicade Summary of Product Characteristics. 5. Cimzia Summary of Product Characteristics. 6. Simponi Summary of Product Characteristics. 7. Remicade EMA report. 8. www.clinicaltrials.gov. Date accessed: May 2016. 9. <http://www.ncbi.nlm.nih.gov/pubmed>. Date accessed: May 2016. 10. Data on File. January 2015. 11. Data on File, February 2016.

Date of preparation: March 2017. PP-ENB-IRL-0145



PROGRAMME ISR Spring Meeting 7th April 2017, Strand Hotel Limerick

- 09.00 CAG meeting - Clinical Programme Rheumatology Lead:
Prof **David Kane**
Chair: **Dr A Fraser**
- 09.00 **Coffee and Registration**
- 09.55 **Welcome**
Dr A Fraser ISR President
- 10.00 **Prof Maya Buch** Professor of Rheumatology and Honorary Consultant Rheumatologist
at The University of Leeds, UK
"Navigating the biologic drug landscape in rheumatoid arthritis – what progress have we made?"
- 11.00 **Prof Gerry Wilson** Arthritis Ireland Professor of Rheumatology UCD
"Update on RABRI"
- 11.15 **Coffee and meet Pharma colleagues**
- 11.45 **Nóirín Nealon Lennox** Health Psychologist
Helen Rooney Chartered Physiotherapist
*"Interdisciplinary Group Acceptance and Commitment Therapy (ACT)
for Chronic Pain in Rheumatology Services: The Evidence, Model and Processes".*
- 12.15 **Prof Austin Stack** Professor of Medicine and Consultant Nephrologist University Hospitals Limerick
"Hyperuricaemia and Chronic Kidney Disease": New Insights, Targets and Strategies
- 13.00 **Lunch and meet Pharma colleagues**
- 14.15 **Dr Philip Hodnett** Consultant Musculoskeletal Radiologist
University Hospitals Limerick
"Imaging of Groin, Hip and Pseudo Hip Pain"
- 15.15 **Prof Howard Amital**
Sackler Faculty of Medicine
Tel Aviv University
"New treatment options in RA: Where is the role for JAK Inhibitors in treatment guidelines".
- 16.15 **Close of Meeting**

FIGHT BACK AGAINST RAPIDLY PROGRESSING RA



ACPA positivity is a poor prognostic factor commonly linked to radiographic progression in early RA^{1,2,3}

Orencia is the only licensed biologic that acts early in the inflammation cascade, specifically targeting T-cell activation. This deactivates B-cells and reduces ACPA levels^{4,5,6}

In AMPLE, Orencia demonstrated similar efficacy to adalimumab in protection against joint erosion and reduction in disease activity⁷

In post hoc analyses, Orencia demonstrated results not seen in the adalimumab arm:

- Greater DAS reduction in high ACPA positive versus low ACPA positive patients⁸
- Continued decline in ACPA levels over 2 years in patients with major clinical response^{9*}

Consider ORENCIA® as your first choice biologic for rapidly progressing RA

For more information, visit www.orencia.co.uk



ORENCIA® (abatacept) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing.

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.

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 and ADMINISTRATION: Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. **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 > 100 kg: 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 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 without 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, see SmPC. **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:** 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. **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), rhinitis, pneumonia, influenza, leukopenia, headache, dizziness, paraesthesia, conjunctivitis, hypertension, flushing, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), alopecia, pruritus, pain in extremity, 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, pelvic inflammatory disease*, basal cell and squamous cell carcinoma, skin papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, bronchospasm, wheezing,

dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, erythema, hyperhidrosis, arthralgia, amenorrhea, menorrhagia, influenza like illness, weight increased. **Rare (≥ 1/10,000 to < 1/1,000):** Tuberculosis, bacteraemia, gastrointestinal infection, lymphoma, lung neoplasm malignant, throat tightness. [*Orencia SC] See SmPC for information on other undesirable effects.

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER: Orencia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack; Orencia 125 mg solution for Injection - EU/1/07/389/008, 4 pre-filled syringes with needle guard and EU/1/07/389/11, ClickJect 4 pre-filled pens.

MARKETING AUTHORISATION HOLDER:

Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK.

FURTHER INFORMATION FROM: Bristol-Myers Squibb Pharmaceuticals, Watery Lane, Swords, Co. Dublin, Tel: 1-800-749-749 or medical.information@bms.com.

DATE OF PREPARATION: August 2016

Job No: 427IE1600247-01

Reporting of 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 Freepost, 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 reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com

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ABBREVIATIONS: RA, Rheumatoid Arthritis; DMARD, Disease Modifying Anti-Rheumatic Drugs; ACPA, anti-citrullinated protein antibodies.

*Major Clinical Response at Day 729 (MCR729) = defined as ACR70 response for a minimum of 6 consecutive months.

DATE OF APPROVAL: March 2017
427IE1700791-01



Speakers

Prof Maya Buch

Professor of Rheumatology and Honorary Consultant Rheumatologist at The University of Leeds, UK



Dr. Maya H Buch PhD, FRCP Prof. Maya H Buch is Professor of Rheumatology and Honorary Consultant Rheumatologist; Deputy Director of the Leeds Institute of Rheumatic & Musculoskeletal Medicine and Section Head, Clinical & Translational Rheumatology at Chapel Allerton Hospital, University of Leeds, UK. Having obtained her medical qualification from the University of Birmingham, UK, followed by internal medicine training, also in Birmingham, Prof. Buch commenced specialist rheumatology training in Leeds. She completed a PhD on investigation of the differential response to TNF-inhibitors in rheumatoid arthritis (RA) and subsequently undertook a Clinical Research Fellowship at the University of Michigan Hospitals Scleroderma Program, Ann Arbor, USA, before completing her specialist rheumatology training in Leeds as a clinical lecturer. Prof. Buch has extensive experience in immunotherapies in autoimmune disease. Her research programme focuses on the investigation and stratification of immunotherapies in RA and its role in the improvement of cardiovascular risk, towards improving the outcomes and lives of people with RA. She directs a broad research portfolio, embracing clinical trials and clinical investigation of factors contributing to therapeutic success or failure as well as mechanistic evaluations to advance understanding of biologic drug response. She also has additional clinical and research interests in the rare disease, scleroderma. She has been involved in several European (EULAR) task force initiatives including the European recommendations on management of RA 92010/2013) and was co-lead author on the updated consensus on rituximab in RA. She sits on the Arthritis Research UK Adult Inflammatory Arthritis Clinical Study Group Steering Committee, was Abstract Chair for EULAR 2014 and Chair of the Scientific Organising Committee, EULAR 2015.

Prof Gerry Wilson

Arthritis Ireland Professor of Rheumatology UCD



Professor Gerry Wilson graduated in Medicine from Queen's University Belfast. He was awarded an ARC Clinical Fellowship for a PhD thesis which he undertook at the University of Sheffield. He was subsequently awarded an ARC Copeman Fellowship for research at Stanford University. He was appointed Professor in Rheumatology and Honorary Consultant Rheumatologist at the University of Sheffield Medical School and Sheffield Teaching Hospitals NHS Foundation Trust where he was Head of the Sheffield EULAR Centre of Excellence for Rheumatology. Prof Wilson was appointed to the Arthritis Ireland/UCD Chair of Rheumatology in 2013. Research interests include genetic and epigenetic influences in RA.

Nóirín Nealon Lennox

Health Psychologist



Nóirín Nealon Lennox is a Practitioner Health Psychologist and ACT trainer. She has specialised in working with people with chronic pain for over a decade. She is a member of the British Psychological Society (BPS) and currently sits on the committee for the Division of Health Psychology (DHP) with the Psychological Society of Ireland (PSI). She is also a member of the Association for Contextual and Behavioural Science (ACBS).

Nóirín has been coordinating and delivering Pain Rehabilitation Programmes for Rheumatology Services in hospitals since 2006. She specialises in a combined Cognitive Behavioural Therapy (CBT) and Acceptance and Commitment Therapy (ACT) approach for patients with

chronic pain. Having originally trained in ACT at the Royal National Hospital for Rheumatic Diseases (RNHRD) in Bath, UK, she continued to develop her practice and trained with the founding members of ACT. More recently, she was commissioned by the HCPC to deliver ACT training to healthcare professionals throughout Ireland. She is also certified in motivational interviewing (MI) and mindfulness based stress reduction (MBSR), and continues to develop and deepen her own personal mindfulness practice. She has carried out research examining the processes and outcomes of ACT rehabilitation for patients suffering with chronic pain and she has presented her research at Psychology and Rheumatology Conferences in Ireland and Europe. She holds a part time lecturing post at the Graduate Entry Medical School (GEMS) at University Limerick.

Helen Rooney

Chartered Physiotherapist



Helen Rooney is a Chartered Physiotherapist. She graduated from NUI Galway in 1996 with a BSc in Microbiology / Biochemistry, she also holds a Hdip in Microbiology and worked in the Biopharma sector for six years. In 2006 she completed a BSc in Physiotherapy from University Limerick. Since then she has primarily worked in the HSE North Tipperary/ East Limerick with some Private Clinical Practice. She is a member of the Irish Society of Chartered Physiotherapists.

Helen's clinical interests are in musculoskeletal pain and associated injury, with a specific interest in chronic pain. Over the last three years Helen has coordinated and delivered chronic lower back pain programmes within her HSE region. Concurrently she is a member of a working group tasked with standardising chronic lower back pain services across the region. More recently, Helen has been the Physiotherapy lead in the delivery of Pain Rehabilitation Programmes for Rheumatology Services in Croom, Co Limerick since its establishment in 2015. Her methodology centers on the Acceptance and Commitment Therapy (ACT) approach for patients with chronic pain. Her current appointment is that of MSK Clinical Specialist in Orthopaedic and Rheumatology services in Croom Hospital.

Prof Austin Stack

Professor of Medicine and Consultant Nephrologist University Hospitals Limerick



Professor Austin Stack is Foundation Chair of Medicine at the Graduate Entry Medical School (GEMS), University of Limerick and Consultant Nephrologist at University Hospital Limerick in Ireland.

He received his medical degree from University College Dublin and completed his post graduate training at the Mater and Beaumont Hospitals followed by clinical and research fellowships at the University of Michigan, USA. He trained in epidemiology and health outcomes research at the Kidney Epidemiology and Cost Centre (KECC) and the United States Renal Data System (USRDS) Coordinating Centre and was Assistant Professor at the University of Texas Medical School in Houston, Texas. In 2016, he was appointed Director of the newly established Health Research Institute (HRI) at the University of Limerick.

His research focus on risk factors, complications and treatment strategies for chronic kidney disease and acute kidney injury. He has published widely in these areas and is PI for several large-scale studies that examine the burden, progression and impact of CKD and AKI in the Irish Health System. He is co-investigator for the CKD surveillance programme in the US and sits on several national and international steering committees and advisory groups. He was instrumental in establishing Ireland's first National Renal Information System and now leads the first National Surveillance System for Kidney Disease. He sits on the Editorial Board for BMC Nephrology and Journal of Nephrology is a reviewer for several major nephrology journals. His work has been funded by the



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American Heart Association, National Institutes of Health, Health Research Board and he serves as a reviewer for NIH, Wellcome Trust UK, and the Chief Scientist Office for Research Scotland.

Dr Philip Hodnett

Consultant Musculoskeletal Radiologist

Dr. Philip Hodnett is a Consultant Musculoskeletal Radiologist in UHL. Upon completion of his FFRCSI in 2008, he undertook MRI Fellowship training in Northwestern Memorial Hospital, Chicago followed by MSK Diagnostic and MSK Intervention Fellowship training in NYU Langone, NYU Hospital for Joint Diseases in NYU. Clinical research includes state of the art emerging and now established MRI sequences with multiple awards, peer review papers and book chapters on unenhanced MRA techniques, chronic exertional compartment syndrome, Muscle injury and Overuse Hip injuries. The interventional MSK and Sports Injury Radiology service in Limerick performs Fluoroscopic, Ultrasound and CT Guided procedures including lumbar, thoracic, cervical transforaminal, caudal epidural, facet joint, sacroiliac joint, ligamentous, tendinous steroid anaesthetic injection, peripheral nerve blocks, PRP and prolotherapy with a rhizotomy service commencing May 2017. Recent awards include induction as Fellow of the Faculty of Sports and Exercise Medicine and invitation to present at the 2017 RCSI Charter Day. He reviews for the European Congress of Radiology, Skeletal Radiology amongst other papers.



Prof Howard Amital

Sackler Faculty of Medicine, Tel Aviv University

Howard Amital MD MHA, specialist in Internal Medicine and Rheumatology. He is Head of the Department of Medicine 'D' at the Meir Medical Center, Kfar-Saba, Israel and Senior Lecturer at the Sackler Faculty of Medicine, Tel-Aviv University, Israel.



ISR Board members

Dr Sandy Fraser

President

Consultant Rheumatologist, General Physician and Honorary Senior Lecturer, University Hospitals Limerick. Dr. Alexander Fraser graduated in medicine from Trinity College Dublin in 1991. He began practicing Rheumatology in 1996 and the following year was appointed Specialist Registrar in Rheumatology at the Yorkshire Deanery. Training with Professor Emery's group in Leeds he developed a research interest in clinical, immunological and therapeutic aspects of Rheumatoid Arthritis, Psoriatic Arthritis and the Sero-negative Spondyloarthropathies. He was appointed Consultant Rheumatologist and Honorary Senior Lecturer at the Leeds Teaching Hospitals NHS Trust, working at The Leeds General Infirmary and St. James' University Hospital in October 2001, and working closely with Professor Emery and Professor Doug Veale he published in the area of Angiogenesis, Vascularity and Inflammation in early and established arthritis and Biomarkers of cartilage turnover. Dr Fraser took up his current appointment as Consultant Rheumatologist, General Physician and Honorary Senior Lecturer at the University Hospitals Limerick in 2006. In conjunction with the University of Limerick Graduate Entry Medical School (GEMS) Dr. Fraser and his team have continued their strong academic interests while managing a busy clinical practice.



Professor David Kane

Prof David Kane attended medical school at Trinity College, Dublin, Ireland and was conferred MB BCH BAO BA in 1991, PhD in 2002 and FRCPI in 2006. He has trained in rheumatology with Prof. Barry Bresnihan and Prof. Oliver FitzGerald at St. Vincent's University Hospital, Dublin, Ireland and with Prof Roger Sturrock, Prof Iain McInnes and Dr Peter Balint at Glasgow Royal Infirmary, Glasgow, United Kingdom. He was appointed as Senior Lecturer in Rheumatology at the University of Newcastle (2003-2005) and is currently working as Consultant Rheumatologist at the Adelaide and Meath Hospital and Clinical Professor in Rheumatology at Trinity College Dublin. His special interests are musculoskeletal ultrasound, spondyloarthopathy and synovial inflammation. He is a member of the European Working Party on Musculoskeletal Ultrasound and the OMERACT special interest group on musculoskeletal ultrasound, previous organiser of the BSR Musculoskeletal Ultrasound course and is Faculty member of the EULAR Musculoskeletal ultrasound course. He has served as a Board member of the Irish Osteoporosis Society, as President and Treasurer of the Irish Society for Rheumatology and is currently a Board member of Arthritis Ireland.



Dr Frances Stafford

Frances is a graduate of UCD, spent almost a decade in North America, training in Rheumatology first at University of Toronto, followed by a fellowship at Massachusetts General Hospital & Harvard Medical School. She was awarded a 4 year Arthritis Foundation Postdoctoral Fellowship, which I completed at the NIH, and then went on staff at the NIH. Frances is American Board Certified in Internal Medicine and in Rheumatology. She has been Consultant at Blackrock Clinic since 1995.



Dr Sinéad Harney

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.



Prof 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 initiated 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.



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Remicade® 100mg Powder for Concentrate for Solution for Infusion (infliximab) Prescribing Information [Refer to full SPC text before prescribing Remicade (infliximab)] **Indications:** Rheumatoid Arthritis (RA): Remicade, in combination with methotrexate (MTX), is indicated for the reduction of signs and symptoms, as well as the improvement in physical function, in adult patients with active RA when the response to disease-modifying anti-rheumatic drugs (DMARDs), including MTX, has been inadequate; and in adult patients with severe, active and progressive disease not previously treated with MTX or other DMARDs. In these patients, a reduction in the rate of the progression of joint damage, as measured by X-ray, has been demonstrated. **Adult Crohn's Disease (CD):** Remicade is indicated for the treatment of moderately to severely active CD in adult patients who have not responded to, or are intolerant of, a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; and fistulising active CD in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). **Paediatric Crohn's Disease (CD):** Remicade is indicated for the treatment of severe, active CD in children and adolescents aged 6 to 17 years who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. **Ulcerative Colitis (UC):** Remicade is indicated for the 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. **Paediatric Ulcerative Colitis (UC):** Remicade is indicated for treatment of severely active UC, in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies. **Ankylosing Spondylitis (AS):** Remicade is indicated for the treatment of severe, active AS, in adult patients who have responded inadequately to conventional therapy. **Psoriatic Arthritis (PsA):** Remicade is indicated for the treatment of active and progressive PsA, in adult patients when the response to previous DMARD drug therapy has been inadequate. Administration should be in combination with MTX or alone in patients who show intolerance to MTX or for whom MTX is contraindicated. A reduction in the rate of progression of peripheral joint damage in patients with polyarticular symmetrical subtypes of PsA has been measured by X-ray. **Psoriasis (PsO):** Remicade is indicated for the treatment of moderate to severe plaque PsO in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, MTX or PUVA. **Dosage and administration:** To improve the traceability of biological medicinal products, the trademark and the batch number of the administered product should be clearly recorded in the patient file. Remicade should be administered intravenously, initiated and supervised by physicians experienced in the diagnosis and treatment of RA, CD, UC, AS, PsA and PsO. Remicade should be administered intravenously over a 2 hour period. All patients administered Remicade should be observed for at least 1 to 2 hours post infusion for acute infusion-related reactions by appropriately trained healthcare professionals. **Shortened infusions across adult indications:** In carefully selected adult patients who have tolerated at least 3 initial 2-hour infusions of Remicade (induction phase) and are receiving maintenance therapy, consideration may be given to administering subsequent infusions over a period of not less than 1 hour. If an infusion reaction occurs in association with a shortened infusion, a slower infusion rate may be considered for future infusions if treatment is to be continued. **Shortened infusions at doses >6 mg/kg have not been studied.** **RA:** 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. **Adult moderately to severely active CD:** 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion. If a patient does not respond after 2 doses, no additional treatment should be given. **Adult fistulising, active CD:** 5 mg/kg intravenous infusion followed by additional 5 mg/kg infusions at 2 and 6 weeks after first infusion. If a patient does not respond after 3 doses, no additional treatment should be given. **UC:** 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. Clinical response is usually achieved within 14 weeks of treatment (3 doses). **AS:** 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 6 to 8 weeks. If a patient does not respond after 2 doses, no additional treatment should be given. **PsA:** 5 mg/kg given as an intravenous infusion period followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. **PsO:** 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. If a patient shows no response after 4 doses, no additional treatment should be given. **Readministration:** Remicade can be readministered within 16 weeks following the last infusion. The safety and efficacy of readministration after a Remicade-free interval of more than 16 weeks had not been established in either CD or RA. The safety and efficacy of readministration in AS, other than every 6 to 8 weeks and in PsA and UC, other than every 8 weeks, has not been established. Readministration with one single Remicade dose in PsO after an interval of 20 weeks suggests reduced efficacy and a higher incidence of mild to moderate infusion reactions when compared to the initial induction regimen. Limited experience from retreatment, using a readministration regimen suggests a higher incidence of infusion reactions, some serious, when compared to 8 weekly maintenance treatment. In case maintenance therapy is interrupted in any indication, and there is a need to restart treatment, Remicade should be reinitiated as a single dose followed by the maintenance dose recommendations. **Paediatric population CD (6 to 17 years):** 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. If a patient does not respond by 10 weeks, no additional treatment should be given. **UC (6 to 17 years):** 5 mg/kg given as an intravenous infusion over a 2-hour period followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data do not support further infliximab treatment in paediatric patients not responding within the first 8 weeks of treatment. **Contra-indications:** Tuberculosis or other severe infections such as sepsis, abscesses and opportunistic infections; patients with a history of hypersensitivity to infliximab, other murine proteins or any of the excipients; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** **Infusion reactions:** Acute infusion reactions including anaphylactic reactions may develop during (within seconds) or within a few hours following infusion. If acute infusion reactions occur, the infusion must be interrupted immediately. Emergency equipment such as adrenaline, antihistamines, corticosteroids and an artificial airway must be available. Antibodies to infliximab may develop and have been associated with increased frequency of infusion reactions. Symptomatic treatment should be given and further Remicade infusions must not be administered. In clinical studies, delayed hypersensitivity reactions have been reported. Available data suggest an increased risk for delayed hypersensitivity with increasing Remicade-free intervals. **Infections:** Patients must be monitored closely for infections, including tuberculosis, before, during and up to 6 months after treatment with Remicade. Exercise caution with use of Remicade in patients with chronic infection or a history of recurrent infection. Patients should be advised of potential risk factors for infections. Suppression of TNF α may mask symptoms of infection such as fever. Tuberculosis, bacterial infections including sepsis and pneumonia, invasive fungal, viral and other opportunistic infections, have been observed, some of which have been fatal. Infections were reported more

frequently in paediatric populations than in adult populations. There have been reports of active tuberculosis in patients receiving Remicade. Patients should be evaluated for active or latent tuberculosis before Remicade treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active tuberculosis is diagnosed, Remicade therapy must not be initiated. If latent tuberculosis is diagnosed, treatment with anti-tuberculosis therapy must be initiated before initiation of Remicade. Patients on Remicade treatment should be advised to seek medical advice if symptoms of tuberculosis appear. An invasive fungal infection such as aspergillosis, candidiasis, pneumocystosis, histoplasmosis, coccidioidomycosis or blastomycosis should be suspected in patients if a serious systemic illness is developed, a physician with expertise in the diagnosis and treatment of invasive fungal infections should be consulted at an early stage. Patients with fistulising CD and acute suppurative fistulas must not initiate Remicade therapy until possible source of infection is excluded. **Hepatitis B (HBV) reactivation:** Reactivation of HBV occurred in patients receiving Remicade who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Remicade. **Hepatobiliary events:** Very rare cases of jaundice and non-infectious hepatitis, some with features of autoimmune hepatitis have been observed. Isolated cases of liver failure resulting in liver transplantation or death have occurred. **Vaccinations:** It is recommended that live vaccines not be given concurrently. Prior to initiating Remicade therapy it is recommended that paediatric patients be brought up to date with all vaccinations. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Remicade and is positive for antibodies against double-stranded DNA, treatment must be discontinued. **Neurological events:** Anti-TNF α agents have been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and risks of anti-TNF treatment should be carefully considered before initiation of Remicade therapy. Discontinuation of Remicade should be considered if these disorders develop. **Malignancies and lymphoproliferative disorders:** A risk of the development of lymphomas and other malignancies in patients (including children and adolescents) cannot be excluded. Caution is advised in patients with history of malignancy and in patients with increased risk for malignancy due to heavy smoking. Rare postmarketing cases of hepatosplenic T-cell lymphoma have been reported which were usually fatal. Most Remicade cases have occurred in patients with CD or UC treated concomitantly with AZA or 6-MP. Caution should be exercised in patients with PsO and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Patients with UC at increased risk for, or with a prior history of dysplasia or colon carcinoma should be screened for dysplasia before therapy and at regular intervals throughout their disease course. Melanoma and Merkel cell carcinoma have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart failure:** Remicade should be used with caution in patients with mild heart failure (NYHA class I/II) and discontinued in face of new or worsening symptoms of heart failure. **Others:** Patients requiring surgery whilst on Remicade therapy should be closely monitored for infections. **Haematologic reactions:** Discontinuation of Remicade therapy should be considered in patients with confirmed significant haematologic abnormalities, including pancytopenia, leucopenia, neutropenia and thrombocytopenia. **Special populations:** Particular attention should be paid when treating the elderly (>65 years) due to a greater incidence of serious infections seen in Remicade treated patients. Some of these had a fatal outcome. **Interactions:** No interaction studies have been performed. Combination of Remicade with other biological therapeutics used to treat the same conditions as Remicade, including anakinra and abatacept is not recommended. It is recommended that live vaccines and therapeutic infectious agents should not be given concurrently with Remicade. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Remicade treatment. Administration of Remicade is not recommended during pregnancy or breastfeeding. Administration of live vaccines to infants exposed to infliximab in utero is not recommended for 6 months following the mother's last infliximab infusion during pregnancy. Effects of infliximab on fertility and general reproductive function are unknown. **Side effects:** **Very Common (>1/10):** Viral infection, headache, upper respiratory tract infection, sinusitis, abdominal pain, nausea, infusion related reaction, pain. **Common (>1/100 to <1/10):** Bacterial infections, neutropenia, leucopenia, anaemia, lymphadenopathy, allergic respiratory symptom, depression, insomnia, vertigo, dizziness, hyposensitivity, paraesthesia, conjunctivitis, tachycardia, palpitation, hypotension, hypertension, ecchymosis, hot flush, flushing, lower respiratory tract infection, dyspnoea, epistaxis, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, hepatic function abnormal, transaminases increased, new onset or worsening psoriasis including pustular psoriasis (primarily palm & sole), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, arthralgia, myalgia, back pain, urinary tract infection, chest pain, fatigue, fever, injection site reaction, chills and oedema. In phase 3 clinical studies, 18% of infliximab-treated patients compared with 5% of placebo-treated patients experienced an infusion related reaction. In post-marketing spontaneous reporting, infections are the most common serious adverse event. The most frequently reported opportunistic infections with a mortality rate of >5% include pneumocystosis, candidiasis, listeriosis and aspergillosis. **Other less common and rarely reported side effects are listed in the SPC.** **Overdose:** No case of overdose has been reported. Single doses up to 20 mg/kg have been administered without toxic effects. **Packaging Quantities:** Type I vials, with rubber stoppers and aluminium crimps protected by plastic caps, containing a lyophilised powder (infliximab 100mg). **Legal Category:** POM. **Marketing Authorisation Number:** EU/1/99/116/001. **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands. **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: 01-2987800).** Date of Revision: June 2014. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. © Merck Sharp & Dohme Ireland (Human Health) Limited, 2014. All rights reserved. Date of preparation: March 2015.

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: 01-2987800)



MSD

Red Oak North, South County Business Park,
Leopardstown, Dublin 18, Ireland



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 John Ryan

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 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 Eamonn Molloy

Eamonn Molloy graduated from University College Dublin (1997) and completed rheumatology and internal medicine training in Ireland. He obtained an MD at RCSI (2006), which focused on calcium crystal induced inflammation. From 2005, he underwent subspecialty fellowship training in vasculitis at the Cleveland Clinic, completed a MS (Clinical Research) at Case Western Reserve University and then joined the staff at the Vasculitis Center and RJ Fasenmeyer Center for Clinical Immunology at the Cleveland Clinic. In 2010, he was appointed as a consultant rheumatologist at St Vincent's University Hospital and is a UCD Senior Clinical Lecturer. He is the author of approximately 50 publications largely pertaining to vasculitis, complications of biologic therapy and crystal induced arthritis. Currently, his primary research focus is giant cell arteritis.



Dr Carl Orr

Carl Orr is a graduate of RCSI, completing his undergraduate studies in 2008 with Honours and later interning and undertaking basic specialist training at Beaumont Hospital. He entered Higher Specialist Training in Rheumatology in 2012. Currently working at the Mater Hospital, he has recently been the Clinical Newman Fellow in Rheumatoid Arthritis at UCD, and has successfully defended his PhD. Carl has presented at many International and National Rheumatology meetings, as well as publishing his work in leading peer-review journals. Following the completion of his Masters in Leadership and Management Development, he has recently been recognised for delivering innovation in rheumatology clinics by the Bernard Connor Award."



Dr Clare Matthews

Consultant Rheumatologist
Ulster Hospital, Belfast



Autumn Meeting 2016



Dr Len Harty



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Cosentyx®

- The first and only fully human IL-17A inhibitor approved for the treatment of psoriatic arthritis, ankylosing spondylitis and psoriasis¹
- Rapid and sustained efficacy in PsA and AS patients, with benefits maintained through 2 years²⁻⁷
- Up to 80% of patients had no radiographic progression on joints and spine^{*3,8}
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SHOW MY FAMILY THAT I CAN STILL BE MYSELF.

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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 and 3, followed by monthly maintenance dosing starting at Week 4. *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 and 3, followed by monthly maintenance dosing starting at Week 4. 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 and 3, followed by monthly maintenance dosing starting at Week 4. 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). 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. *Crohn's disease:* Caution should be exercised when prescribing to patients with Crohn's disease as exacerbations of Crohn's disease, in some cases serious, were observed in clinical studies. Close monitoring of patients with Crohn's disease treated with Cosentyx. **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. No interaction studies have been performed in humans. A clinically relevant effect on CYP450 substrates with a narrow therapeutic index, where the dose is individually adjusted (e.g. warfarin) cannot be excluded. Therapeutic monitoring should be considered on initiation in patients treated with these types of medicinal products. 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, Frimley Business Park, Camberley, GU167SR, United Kingdom. **Marketing Authorisation Numbers:** EU/1/14/980/004-005. **Date of Revision of Abbreviated Prescribing Information:** November 2015. 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>. **References:** 1. Cosentyx Summary of Product Characteristics, April 2016. 2. Mease PJ et al. Presented at the American College of Rheumatology 2016. Presentation number 961. 3. Braun J et al. Ann Rheum Dis. 2016 Dec 13. pii: annrheumdis-2016-209730. doi: 10.1136/annrheumdis-2016-209730. 4. Strand V, et al. Ann Rheum Dis. 2016;doi:10.1136/annrheumdis-2015-2090553. 5. Novartis Data on File 2014. F2312_Patient assessment of pain through 24 weeks_Table 14.2-12.1. 6. Novartis Data on File 2014. F2305_Total spinal pain through 24 weeks_Table 14.2-12.1. 7. Novartis Data on File 2014. F2310_Total spinal pain through 16 weeks_Table 14.2-12.1. 8. Mease P et al. Arthritis Rheum 2015; 67 (S10): 2576. Oral presentation 2148 at the American College of Rheumatology (ACR), 9 November 2015, San Francisco, USA. 9. van de Kerkhof P et al. J Am Acad Dermatol 2016; 75(1): 83-98. 10. European Medicines Agency Public Assessment Report. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/003729/WC500183131.pdf. *Patients received intravenous secukinumab (10 mg per kg of body weight) or matched placebo at weeks 0, 2, and 4, followed by subcutaneous secukinumab (150 mg or 75 mg) or matched placebo every 4 weeks starting at week 8. **Date of Preparation:** March 2017. IE02/COS16-CNF010d

 **NOVARTIS**
PHARMACEUTICALS



IRHPS Spring 2017 Update

Welcome to the Spring Conference 2017.

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 Kildare last September with presentations on managing pregnancy in rheumatic disease by Dr Anita Banerjee, the challenges of parenting in rheumatic disease by Dr Helene Mitchell and exercise for bone health by Dr Caitriona Cunningham.

The 2 highest scoring IRHPS abstract submissions also presented their work – many thanks to Noreen Harrington, RANP, Our Lady's Hospital, Manorhamilton and Trish Fitzgerald, Senior Occupational Therapist, SVUH.

Congratulations also to our poster prize winners Noreen Lennox, Rachel Burke, Eileen O'Flynn and Sean McKenna and also to Yvonne Codd 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



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...with just 4 maintenance doses per year^{6*}

* following a loading dose at week 0 and week 4

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STELARA 45 mg and 90 mg solution for injection and 130 mg concentrate for solution for infusion. **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 disease-modifying 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 either conventional therapy or TNF α 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 <100 kg, 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 – <100 kg, 45 mg at week 0 followed by 45 mg at week 4, then every 12 weeks. Patients >100 kg, 90 mg at week 0, followed by 90 mg 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 0.9% w/v 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 immunosuppressive biologic 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. 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 immunosuppressive 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):** 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:** 11/2016

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 +44 1494 567447 or at dsafety@its.jnj.com.

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

PHIR/STE/0317/0001 | Date of Preparation: March 2017



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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. No data is available regarding the safety of febuxostat during cytotoxic chemotherapy. **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 indometacin 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, haematocrit decrease, blood lactate dehydrogenase increased, blood potassium increase. **Rare (0.1-0.01%):** Pancytopenia, thrombocytopenia, 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 morbilliform, 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 2017.

References: 1. Adenuric 80 mg SmPC, January 2017. 2. Adenuric 120 mg SmPC, January 2017.

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Date of item: February 2017
IR-ADEN-03-2017



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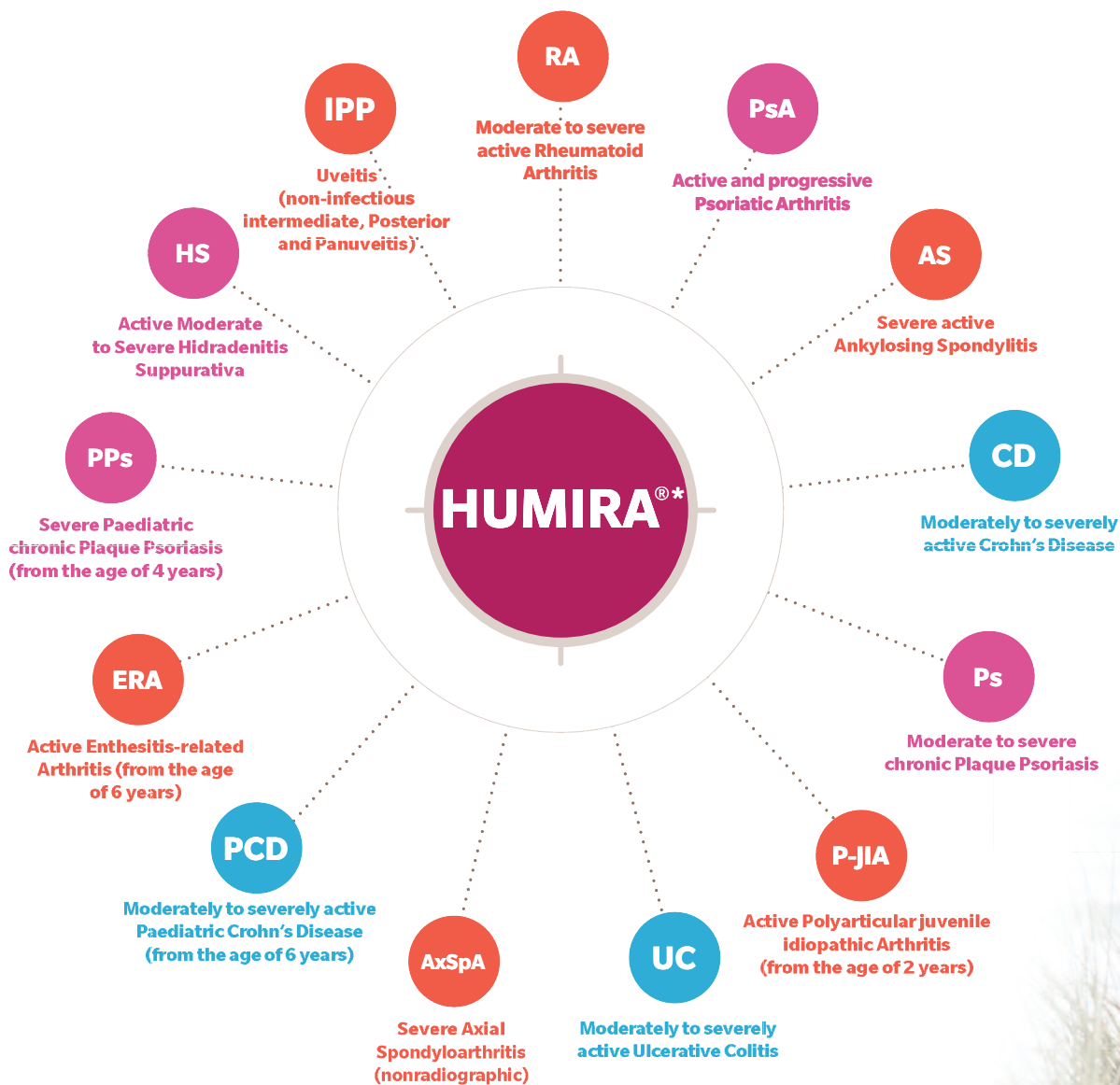
Prescribing Information

Humira (adalimumab) 40mg solution for injection in pre-filled pen or pre-filled syringe or Humira 40mg/0.8ml solution for injection for paediatric use.

*** Refer to Summary of Product Characteristics (SmPC) for full information.**

Presentation: Each 0.4ml single dose pre-filled pen or pre-filled syringe contains 40mg of adalimumab. Each 0.8ml single dose vial contains 40mg of adalimumab. **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 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; or 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. 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. 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 (NSAIDs). Crohn's disease (CD), adults: For moderately to severely, active CD with inadequate response, contraindication or intolerance to corticosteroid and/or an immunosuppressant therapy. Crohn's disease (CD), Paediatrics 6 years and above: For moderately to severely active CD with inadequate response, contraindication or intolerance to conventional therapy including primary nutrition therapy and a corticosteroid, and/or an immunomodulator. Psoriasis (Ps), adults: For moderate to severe chronic plaque psoriasis who are candidates for systemic therapy. Psoriasis, paediatrics 4 years and above: For severe chronic plaque psoriasis with inadequate response, or if topical therapy and phototherapies are inappropriate. Hidradenitis suppurativa (HS), adults: For active moderate to severe hidradenitis suppurativa (acne inversa) in patients with an inadequate response to conventional systemic HS therapy. Ulcerative colitis (UC), adults: For moderately to severely active UC with inadequate response, contraindication or intolerance to 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 need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **Dosage and administration:** Specialist physicians experienced in the diagnosis and treatment of the condition, to initiate and supervise treatment. Ophthalmologists to consult with an appropriate specialist before initiation of treatment. Provide patients with special alert card. Patients may self-inject after proper injection training, with physician approval and appropriate medical follow-up. Optimise other concomitant therapies. RA adults: 40mg dose every other week. Concomitant MTX should be continued. During monotherapy patients may require 40mg each week 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. Re-introduction after 70 days dose interruption gave same magnitudes of clinical response and similar safety profile as before dose interruption. pJIA, paediatrics 2 years and above: pJIA, paediatrics 2-4 years: 24mg/m² body surface area up to 20mg maximum single dose every other week (see SmPC for height/weight dosing chart). pJIA, paediatrics 4-12 years: 24mg/m² body surface area up to 40mg maximum single dose every other week (see SmPC for height/weight dosing chart). pJIA, paediatrics 13 years and above: 40mg every other week regardless of body

surface area. Treatment beyond 12 weeks reconsidered if no clinical response in that time. ERA, paediatrics 6 years and above: 24mg/m² body surface area up to a maximum single dose of 40mg every other week. (see SmPC for height/weight dosing chart). PsA, AS and nr-axSpA, adults: 40mg every other week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. CD, Adults: Induction: 80mg at Week 0 followed by 40mg at Week 2. For a more rapid response, 160mg at Week 0 (either as 4 injections in 1 day or 2 injections/day for 2 consecutive days), 80mg at Week 2; risk of adverse events higher during induction. Maintenance: 40mg every other week. If decrease in clinical response, can increase dose to 40mg weekly. Corticosteroids may be tapered in maintenance phase in accordance with clinical guidelines. Patients with no response by Week 4 may benefit from continued therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. CD, paediatrics 6 years and above <40Kg: Induction: 40mg at Week 0, 20mg at Week 2. For a more rapid response: 80mg at Week 0 (2 injections in 1 day), 40mg at Week 2; risk of adverse events higher during induction. Maintenance: 20mg every other week. If insufficient response, consider 20mg every week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. CD, paediatrics 6 years and above >40Kg: Induction: 80mg Week 0, 40mg at Week 2. For a more rapid response: 160mg at Week 0 (4 injections in 1 day or 2 injections/day for 2 consecutive days), 80mg at Week 2; risk of adverse events higher during induction. Maintenance: 40mg every other week. If insufficient response, consider 40mg every week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Psoriasis, adults: 80mg induction dose at week 0, 40mg every other week 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 dosing frequency to 40mg every week. If adequate response is achieved with an increased dosing frequency, dose may subsequently be reduced to 40mg every other week. If there is inadequate response to the increased frequency, carefully reconsider treatment. Psoriasis, Paediatrics 4 years and above: 0.8mg per kg body weight (maximum of 40mg/dose) weekly for the first 2 doses and then every other week (see SmPC for weight dosing chart). Treatment beyond 16 weeks should be reconsidered if no response in that time. HS: Adults: 160mg initially at Day 1 (four 40mg injections in one day or two 40mg injections per day for two consecutive days), followed by 80mg two weeks later at Day 15 (two 40mg injections in one day). Two weeks later (Day 29) continue with a dose of 40mg every week. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions should be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Reintroduction after interruption: 40mg every week. Evaluate periodically the benefit and risk of continued long-term treatment. UC: Adults: Induction: 160mg at week 0 (4 injections in 1 day or 2 injections/day for 2 consecutive days) and 80mg at week 2. Maintenance: 40mg every other week. During maintenance, corticosteroids may be tapered in accordance with clinical practice guidelines. If insufficient response, consider 40mg every week. Treatment beyond 8 weeks should be reconsidered if no clinical response in that time. Uveitis: Adults: 80mg induction dose at week 0, 40mg every other week from week 1. Experience of initiating treatment with Humira alone is limited. Treatment can be initiated in combination with corticosteroids and/or other non-biologic immunomodulatory agents. Two weeks after initiating treatment, concomitant corticosteroids may be tapered in accordance with clinical guidelines. Evaluate on a yearly basis, the benefit and risk of continued long term treatment. **Contraindications:** Active tuberculosis (TB), severe infections (e.g. sepsis), and opportunistic infections; moderate to severe heart failure (NYHA class III/IV); hypersensitivity to adalimumab or any of the excipients. **Precautions and Warnings:** Clearly record trade name and batch number of administered product to improve traceability of biological medicinal product. **Infections:** Patients 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 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. **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. 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 has occurred in chronic carriers (i.e. surface antigen positive) 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 and consider stopping treatment if these disorders develop. Rare association with new onset or exacerbation of symptoms and/or radiographic evidence of central and peripheral demyelinating disease. Known association between intermediate uveitis and central demyelinating disorders. Evaluate 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. Monitor all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment for non-melanoma skin cancer prior to and during Humira therapy, 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 for developing dysplasia or colon cancer is unknown. Patients with UC, prior history of dysplasia or colon carcinoma to be screened for dysplasia before therapy 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. **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. 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 whom had fatal outcomes. Consider risk of infection. **Interactions:** Combination of adalimumab with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Fertility, pregnancy and lactation:** Not recommended during pregnancy. Women of childbearing potential should use adequate contraception and continue its use for at least five months after the last Humira treatment. Women must not breast-feed for at least five months after the last treatment. **Side Effects:** Very common $\geq 1/10$: Infections, leucopenia, anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction. **Serious, including fatal, side effects have been reported** including infections/sepsis, intestinal perforation, opportunistic infections, TB, endemic mycoses, demyelinating disease, malignancies including lymphoma (including hepatosplenic T-cell lymphoma), leukaemia and skin cancer (including melanoma and merkel cell carcinoma), cytopenias, worsening heart failure, myocardial infarction, pulmonary embolism, pleural effusion, pulmonary fibrosis, cerebrovascular accident, interstitial lung disease, lupus, Stevens-Johnson syndrome, angioedema, anaphylaxis, sarcoidosis, hepatitis, liver failure and worsening of symptoms of dermatomyositis. **Prescribers should consult the SmPC for the complete list of reported side effects.** **Legal Category:** POM. **Marketing Authorisation Numbers/Presentations:** Vial: EU/1/03/256/001; Pre-filled Syringe: EU/1/03/256/013; Pre-filled Pen: EU/1/03/256/017. Further information is 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 2016 (P/2256/017)

References: 1. HUMIRA [summary of product characteristics]. AbbVie Ltd.
2. Data on File, AbbVie.

Date of Preparation: December 2016
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*** For patients with Rheumatoid Arthritis, Psoriatic Arthritis or Axial Spondyloarthritis²**

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PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SPC) before prescribing.)

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.

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.

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.

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, leucopenia, 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. **Pregnancy and lactation:** Cimzia is not recommended in pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception up to 5 months after the last administered dose.

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 ($\geq 1/100$ 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.

Further information is available from:

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Email: UCBcares.UK@ucb.com

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Email: UCBcares.IE@ucb.com

Date of Revision: 09/2016 (UK/14C1010N/2).

Cimzia is a registered trademark.

UK Specific Information:

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

Date of preparation: November 2016
UK/16C10175

References:

1. UCB data on file (Comparative Usability and Validation Study for CIMZIA® pre-filled pen - Study Report, Sections 11.1.1, 11.2.3, 11.2.4).
2. Cimzia® (certolizumab pegol) Summary of Product Characteristics, September 2016.

ucb Inspired by patients.
Driven by science.

ISR Autumn 2016



Dr Mary Canavan, YI Award – Joint Winner, Dr Sandy Fraser



Dr Anca Smyth, Bernard Connor Medal, Dr Sandy Fraser



Dr Amanda Eakin, YI Award – Joint Winner, Dr Sandy Fraser



Lis Moran and Karen Walsh, AbbVie



Mairead Dockery & Petrina Donohue



PINEWOOD

HEALTHCARE

A Better choice for your patients' health

“Remsima is a New Generation Treatment for Rheumatology”

Remsima is

- ✓ Remsima is a *TNF- α* inhibitor to help rapid reduction in inflammation^{1,2}
- ✓ Remsima helps to reduce the risk of radiographic progression in RA³
- ✓ Remsima is right for your patients through faster and earlier access

[QUALITATIVE AND QUANTITATIVE COMPOSITION] One vial contains 100 mg of infliximab. Infliximab is a chimeric human-murine IgG1 monoclonal antibody produced in murine hybridoma cells by recombinant DNA technology.

[CLINICAL PARTICULARS] 1) Rheumatoid arthritis: Remsima, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate. Adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X-ray, has been demonstrated. 2) Ankylosing spondylitis: Remsima is indicated for treatment of severe, active ankylosing spondylitis, in adult patients who have responded inadequately to conventional therapy. 3) Adult Crohn's disease: Remsima is indicated for treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

Treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). 4) Ulcerative colitis: Remsima is indicated for treatment of moderately to severely active ulcerative colitis 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. 5) Psoriatic arthritis: Remsima is indicated for treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. Remsima should be administered in combination with methotrexate or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated. Infliximab has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease. 6) Psoriasis: Remsima is indicated for treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

[Posology and method of administration] During Remsima treatment, other concomitant therapies, e.g. corticosteroids and immunosuppressants should be optimised.¹⁾

Rheumatoid arthritis 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Remsima must be given concomitantly with methotrexate. Available data suggest that the clinical response is usually achieved within 12 weeks of treatment. If a patient has an inadequate response or loses response after this period, consideration may be given to increase the dose step-wise by approximately 1.5 mg/kg, up to a maximum of 7.5 mg/kg every 8 weeks. Alternatively, administration of 3 mg/kg as often as every 6 weeks may be considered. If adequate response is achieved, patients should be continued on the selected dose or dose frequency. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment or after dose adjustment. 2) Ankylosing spondylitis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. If a patient does not respond after 2 doses, no additional treatment with infliximab should be given. Available data do not support further infliximab treatment, in patients not responding within 6 weeks of the initial infusion. In responding patients, the alternative strategies for continued treatment are: -Maintenance: Additional infusion of 5 mg/kg at 6 weeks after the initial dose, followed by infusions every 8 weeks or re-administration: Infusion of 5 mg/kg if signs and symptoms of the disease recur. Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. 3) Crohn's Disease: 1) Moderately to severely active Crohn's disease: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data suggest that the clinical response is usually achieved within 14 weeks of treatment, i.e. three doses. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. 5) Psoriatic arthritis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. 6) Psoriasis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. If a patient does not respond after 3 doses, no additional treatment with infliximab should be given. In responding patients, the alternative strategies for continued treatment are: -Maintenance: Additional infusions of 5 mg/kg every 8 weeks or re-administration: Infusion of 5 mg/kg if signs and symptoms of the disease recur followed by infusions of 5 mg/kg every 8 weeks. Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after dose adjustment. In Crohn's disease, experience with re-administration if signs and symptoms of disease recur is limited and comparative data on the benefit/risk of the alternative strategies for continued treatment are lacking. 4) Ulcerative colitis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data suggest that the clinical response is usually achieved within 14 weeks of treatment, i.e. three doses. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. 5) Psoriatic arthritis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. 6) Psoriasis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. In clinical studies, delayed hypersensitivity reactions have been uncommon and have occurred after infliximab-free intervals of less than 1 year (see sections 4.4 and 4.8). The safety and efficacy of re-administration after an infliximab-free interval of more than 16 weeks has not been established. This applies to both Crohn's disease patients and rheumatoid arthritis patients.

Re-administration for ulcerative colitis: the safety and efficacy of re-administration, other than every 8 weeks, has not been established. Re-administration for ankylosing spondylitis: the safety and efficacy of re-administration, other than every 6 to 8 weeks, has not been established.

Re-administration for psoriatic arthritis: the safety and efficacy of re-administration, other than every 8 weeks, has not been established. Re-administration for psoriasis: limited experience from re-treatment following disease flare by a re-induction regimen suggests a higher incidence of infusion reactions, including serious ones, when compared to 8 weekly maintenance treatment. **[Contraindications]** Patients with: 1) history of hypersensitivity to infliximab, to other murine proteins, or to any of the excipients 2) tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections 3) moderate or severe heart failure (NYHA class III/IV)



Dr Sinead Harney, Dr John Ryan, CUH



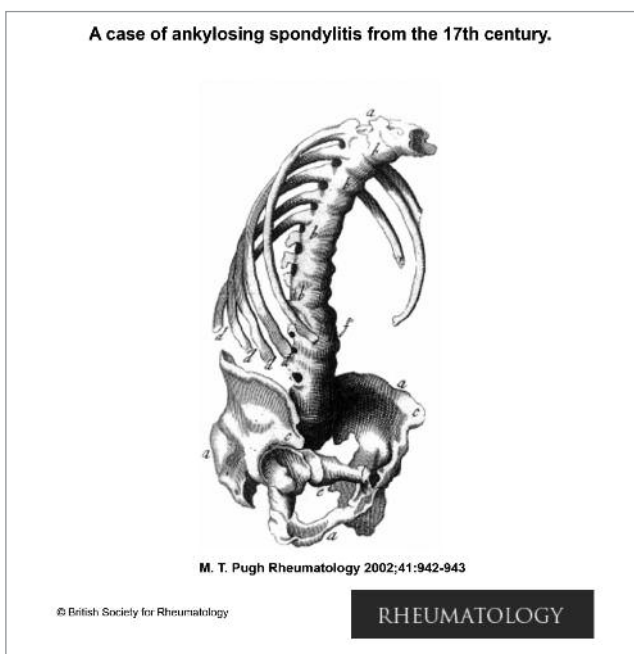
ISR Staff – Helen, Cora, Noelle and Carmel



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. Applicants must be fully registered students of a Medicine Programme (MB degree) in an Irish University (NUIG, QUB, RCSI, TCD, UCC, UCD, UL) on April 1st 2017
OR
2. Irish citizens who are fully registered students of an MB programme in a university outside Ireland on April 1st 2017
3. 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. Applicants must submit completed entries to the ISR by the notified deadline
5. 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

3 July 2017

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 Winners



2015 Dr Eva McCabe NUI Galway

Targeted medical education debunks the myths of back pain



2016 Dr Anca Smyth QUB

Reflections on Patient Reported Flares in Rheumatoid Arthritis

TAPENTADOL PALEXIA[®] SR

...A KEY FOR CHRONIC PAIN



FOR SEVERE CHRONIC PAIN

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



PALEXIA SR[®] PROLONGED RELEASE TABLETS PRESCRIBING INFORMATION

Refer to the Summary of Product Characteristics (SmPC) before prescribing. **PRESENTATION:** 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 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, not divided or chewed, with or without food. 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. **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 hypersomnia). **SPECIAL WARNINGS AND PRECAUTIONS:** At risk patients may require monitoring due to misuse, abuse, addiction or diversion. 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 tumours, moderate hepatic impairment, biliary tract disease including acute pancreatitis. Not recommended if history of or at risk of seizures or with 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:** Use with benzodiazepines, barbiturates and opioid analgesics, antitussive drugs and substitutive treatments may enhance the risk of respiratory depression. Central nervous system (CNS) depressants (e.g. benzodiazepines, antipsychotics, H1-antihistamines, opioids, alcohol) can enhance the sedative effect and impair vigilance. Consider dose reduction with respiratory or CNS depressant agents. In isolated cases, serotonin syndrome has been reported with Palexia SR in combination with serotonergic medicinal products (e.g. serotonin re-uptake inhibitors). Use with strong inhibitors of uridine diphosphate transferase isoenzymes (involved in glucuronidation) may increase systemic exposure of Palexia SR. Risk of decreased efficacy or adverse events if used with strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort). 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 treatment, in connection with alcohol or tranquilisers. **UNDESIRABLE EFFECTS:** *Very common* ($\geq 1/10$): dizziness, somnolence, headache, nausea, constipation. *Common* ($\geq 1/100$, $<1/10$): decreased appetite, anxiety, depressed mood, sleep disorder, nervousness, restlessness, disturbance in attention, tremor, involuntary muscle contractions, flushing, dyspnoea, vomiting, diarrhoea, dyspepsia, pruritus, hyperhidrosis, rash, asthenia, fatigue, feeling of body temperature change, mucosal dryness, oedema. Other important undesirable effects: palpitations, heart rate increased/decreased (*uncommon* $\geq 1/1000$, $<1/100$), drug hypersensitivity including angioedema, anaphylaxis and anaphylactic shock (*uncommon* $\geq 1/1000$, $<1/100$), respiratory depression (*rare* $\geq 1/10,000$, $<1/1000$), convulsion (*rare* $\geq 1/10,000$, $<1/1000$). No evidence of increased risk of suicidal ideation or suicide with 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:** 50 mg: PA 1189/7/4, 28 and 56 packs; 100 mg: PA 1189/7/5, 56 pack; 150 mg: PA 1189/7/6, 56 pack; 200 mg: PA 1189/7/7, 56 pack and 250 mg: PA 1189/7/8, 56 pack. **MARKETING AUTHORISATION HOLDER:** Grünenthal Ltd, Regus Lakeside House, 1 Furzeground Way, Stockley Park East, Uxbridge, Middlesex, UB11 1BD, UK. **DATE OF PREPARATION:** November 2013. IRE/P13 0025b. **REFERENCE:** 1. Palexia SR Summary of Product Characteristics

ISR Autumn 2016

Novartis Ireland Ltd • Pfizer Healthcare Ireland Ltd • Roche Products (Ireland) Ltd • A.Menarini Pharmaceuticals Ltd • Actelion
 Onmel Health Ltd • Eli-Lilly & Co (Ireland) Ltd • Fannin Ltd • Grünenthal Pharma Ltd • Janssen-Cilag Ltd • Lily Rheumatology



Tomás Stack, Roche; Dr Sarah Wade, Oral Prize Winner, Dr Sandy Fraser

Ireland Ltd • Pfizer Healthcare Ireland Ltd • Roche Products (Ireland) Ltd • A.Menarini Pharmaceuticals Ltd • Actelion
 Health Ltd • Eli-Lilly & Co (Ireland) Ltd • Fannin Ltd • Grünenthal Pharma Ltd • Janssen-Cilag Ltd • Lily Rheumatology



Tomás Stack, Roche; Dr Richard Conway, 1st Prize Oral, Dr Sandy Fraser



Alendronic acid 70 mg Effervescent Tablets

**Alendronate designed with
adherence in mind**

**80% of patients stop alendronate
tablet treatment within a year.²**

**NEW Binosto is the first and only
buffered alendronate solution
designed to help minimise gastric
tolerability issues.^{3,4}**

**The big alendronate
adherence problem.^{1,2}**

ABBREVIATED PRESCRIBING INFORMATION

Binosto Once Weekly 70 mg effervescent tablets

Each effervescent tablet contains 70 mg alendronic acid as 91.37 mg of alendronate sodium trihydrate. **Presentation:** White to off-white round effervescent tablets of 25 mm diameter, flat faced with bevelled edges. **Indications:** Treatment of postmenopausal osteoporosis. Binosto 70 mg reduces the risk of vertebral and hip fractures. **Posology and method administration:** The recommended dose is one 70 mg effervescent tablet once weekly. Patients should be instructed that if they miss a dose of Binosto 70 mg, they should take one effervescent tablet on the morning after they remember. **Elderly:** No dosage adjustment is necessary for the elderly. **Renal impairment:** No dosage adjustment is necessary for patients with GFR greater than 35 ml/min. Alendronate is not recommended for patients with renal impairment where GFR is less than 35 ml/min. **Children:** Not recommended for use in children under the age of 18 years. Binosto 70 mg must be taken at least 30 minutes before the first food, beverage, or medicinal product of the day with plain water only. Other beverages (including mineral water), food and some medicinal products are likely to reduce the absorption of alendronate. **Contraindications:** Hypersensitivity to alendronate or to any of the excipients. Abnormalities of the oesophagus and other factors which delay oesophageal emptying such as stricture or achalasia. Inability to stand or sit upright for at least 30 minutes. Hypocalcaemia. **Special warnings and precautions for use:** Patients with active upper gastro-intestinal problems. Oesophageal reactions have been reported in patients receiving alendronate. The risk of severe oesophageal adverse experiences appears to be greater in patients who fail to take alendronate properly and/or who continue to take alendronate after developing symptoms suggestive of oesophageal irritation. Osteonecrosis of the jaw has been reported in patients with cancer receiving treatment regimens including primarily intravenously administered bisphosphonates. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with poor dental status. Bone, joint, and/or muscle pain has been reported in patients taking bisphosphonates. Atypical subtrochanteric and diaphyseal femoral fractures have been reported with bisphosphonate therapy. During bisphosphonate treatment patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete femur fracture. In post-marketing experience of alendronate, there have been rare reports of severe skin reactions including Steven Johnson syndrome and toxic epidermal necrolysis. Alendronate is not recommended for patients with renal impairment where GFR is less than 35 ml/min. Causes of osteoporosis other than oestrogen deficiency and ageing or glucocorticoid use should be considered. Hypocalcaemia must be corrected before initiating therapy with alendronate. Other disorders affecting mineral metabolism (such as vitamin D deficiency and hypoparathyroidism) should also be effectively treated before starting Binosto treatment. Due to the positive effects of alendronate in increasing bone mineralisation, decreases in serum calcium and phosphate may occur especially in patients taking glucocorticoids in whom calcium absorption may be decreased. Ensuring adequate calcium and vitamin D intake is particularly important in patients receiving glucocorticoids. Contains 602.54 mg sodium per dose. **Interaction with other medicinal products and other forms of interaction:** Food and beverages (including mineral water), calcium supplements, antacids, some oral medicinal products. Fertility, pregnancy and lactation: Alendronate should not be used during pregnancy or breast-feeding. Effects on ability to drive and use machines: Certain adverse reactions that have been reported with alendronate may affect some patients' ability to drive or operate machinery. **Undesirable Effects:** (Very common or common) headache, dizziness, vertigo, abdominal pain, dyspepsia, constipation, diarrhoea, flatulence, oesophageal ulcer, dysphagia, abdominal distension, acid regurgitation, alopecia, pruritus, musculoskeletal pain, joint swelling, asthenia, peripheral oedema. Refer to SmPC for other undesirable effects. 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. **Overdose:** Hypocalcaemia, hypophosphataemia and upper gastro-intestinal adverse events, such as upset stomach, heartburn, oesophagitis, gastritis, or ulcer, may result from oral overdosage. No specific information is available on the treatment of overdosage with alendronate. Pack size: 4 effervescent tablets. **Marketing authorisation holder:** Clonmel Healthcare Ltd, Clonmel, Ireland. **Marketing authorisation number:** PA 126/280/1. Full prescribing information is available on request, or go to www.clonmel-health.ie. Medicinal product subject to medical prescription. **Date last revised:** January 2016.

References: 1. Brandi M and Black D. Clinical Cases in Mineral and Bone Metabolism 2013; 10(3): 187-190. 2. Data on file D2. Internis Pharmaceuticals. 2015. 3. Invernizzi M et al. Aging Clin. Exp Res 2015;27:107-113. 4. Hodges LA et al. Int Journal of Pharmaceutics 2012;432:57-62.



Ollie Kinlough, AbbVie; Dr Ali Al Shamsi, Dr Sandy Fraser



Tomás Stack, Roche; Dr Carmel Silke accepting award on behalf of Bernie McGowan; Dr Sandy Fraser

For the treatment of rheumatoid arthritis in adults

NEW

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methotrexate

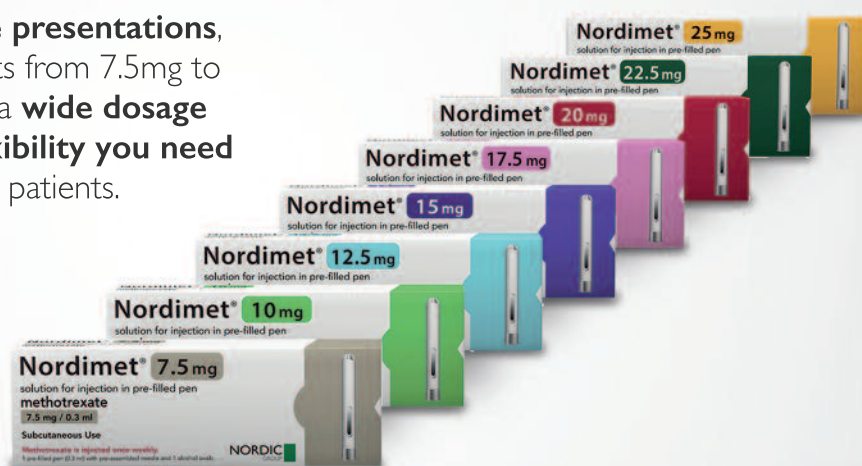


NEW NORDIMET[®] PEN

THE FIRST 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.



NEW 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: Nordimet: 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 should be discussed with male and female patients of childbearing potential. **Interactions:** Consult SPC for detailed information on interactions. **Undesirable effects:** See SmPCs for full list of undesirable effects. **Nordimet:** 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. Severe courses of bone marrow depression. Acute aseptic meningitis. Convulsions. Paralysis. Impaired vision. Retinopathy. Haematemeses. Toxic megacolon. Hepatic failure. Stevens-Johnson syndrome. Toxic epidermal necrolysis. Not known: Eosinophilia. Encephalopathy/Leukoencephalopathy. **Legal classification:** POM. **MA numbers:** Nordimet: EU/1/16/1124/001 – 008. **Further information available from:** Nordic Pharma Ltd, Unit 3, Commerce Park, Brunel Road, Theale, Reading, United Kingdom. **Date of prescribing information:** January 2017. **Code for PI:** NOR/17/001

Adverse events should be reported.

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



Morag Tunstall, Dr Julian Maitland, Dr Sinead Harney & Prof David Kane



Dr John Stack Chairs: Dr Ber Lynch, Dr Donough Howard

Mundipharma Pharmaceuticals Ltd



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Dr Eamonn Molloy



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FN/2016/108/00
Date of Preparation: March 2017

Metoject 50 mg/ml solution for injection, pre-filled syringe (refer to full Summary of product Characteristics before prescribing).
Qualitative and quantitative composition: 1 ml of solution contains 50 mg methotrexate (as methotrexate disodium), 1 pre-filled syringe of 0.15ml (0.20ml, 0.40 ml, 0.50ml) contains 7.5 mg (10 mg; 15 mg; 20 mg; 25 mg) methotrexate. Excipients: sodium chloride, sodium hydroxide, water for injections. **Therapeutic indications:** 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; severe psoriatic arthritis in adult patients. **Posology and method of administration:** Should only be prescribed by physicians who are familiar with the various characteristics of the medicinal product and its mode of action. **Adults, rheumatoid arthritis:** The recommended initial dose is 7.5 mg of Metoject once weekly, administered either subcutaneously, intramuscularly or intravenously. 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 not be exceeded. **Psoriasis vulgaris, psoriatic arthritis:** 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 either subcutaneously, intramuscularly or intravenously. The doses to be increased gradually, but should not, in general, exceed a weekly dose of 25 mg of methotrexate. **Elderly:** Dose reduction should be considered due to reduced liver and kidney function as well as lower folate reserves. If changing from oral methotrexate a reduction in dose may be required due to the variable bioavailability of methotrexate by the oral route. **Contraindications:** Hypersensitivity to methotrexate or any of the excipients; liver insufficiency; alcohol abuse; severe renal insufficiency (creatinine clearance <20ml/min); pre-existing blood dyscrasias; (bone marrow hyperplasia; 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, breastfeeding; concurrent vaccination with live vaccines. **Special warnings and precautions for use:** Patients must be clearly informed that Metoject has to be administered **once a week**. Patients undergoing therapy should be subject to appropriate supervision. Because of the risk 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. **Interactions with other medicines:** Special care should be taken with Methotrexate and Alcohol, other haematotoxic medicinal products, antibiotics, other 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, medicinal 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:** 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:** Stomatitis, dyspepsia, nausea, loss of appetite, common: oral ulcers, diarrhoea. **Uncommon:** pharyngitis, enteritis, vomiting, rare: gastrointestinal ulcers, very rare: hematemeses, haematemesis, toxic megacolon. **Skin and subcutaneous tissue disorders:** common: Exanthema, erythema, pruritus, uncommon: photosensitisation, loss of hair, increase in rheumatic nodules, herpes zoster, vasculitis, herpetic eruptions of the skin, urticaria, **Rare:** increased pigmentation, acne, ecchymosis, **Very Rare:** Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), increased pigmentary changes of the nails, acute paronychia, furunculosis, telangiectasia. **General disorders and administration site conditions:** **Rare:** Allergic reactions, anaphylactic shock, allergic vasculitis, fever, conjunctivitis, infection, sepsis, wound-healing impairment, hypogammaglobulinemia. **Very Rare:** local damage of injection site following intramuscular or subcutaneous administration. **Metabolism and nutrition disorders:** uncommon: Precipitation of diabetes mellitus. **Nervous system disorders:** Common: headache, tiredness, drowsiness, uncommon: dizziness, confusion, depression, **Very rare:** impaired vision, pain, muscular asthenia and paraesthesia in the extremities, changes in sense of taste, convulsions, meningism, paralysis, unknown: Leukoencephalopathy. **Eye disorders:** Rare: Visual disturbances. **Very rare:** retinopathy. **Hepatobiliary disorders:** **Very common:** Elevated transaminases. **Uncommon:** cirrhosis, fibrosis and fatty degeneration of the liver, decrease of serum albumin, **Rare:** acute hepatitis, **Very Rare:** hepatic failure. **Cardiac disorders:** **Rare:** Pericarditis, pericardial effusion, pericardial tamponade. **Vascular disorders:** **Rare:** Hypotension, thromboembolic events. **Respiratory, thoracic and mediastinal disorders:** Common: Pneumonia, interstitial alveolitis/ pneumonitis often associated with eosinophilia, **Rare:** pulmonary fibrosis, pneumocystis carinii pneumonia, shortness of breath and bronchial asthma, pleural effusion. **Blood and lymphatic system disorders:** Common: Leukopenia, anaemia, thrombopenia. **Uncommon:** pancytopenia, **Very rare:** agranulocytosis, severe courses of bone marrow depression. **Renal and urinary disorders:** uncommon: Inflammation and ulceration of the urinary bladder renal impairment, disturbed micturition, **Rare:** renal failure, oliguria, anuria, electrolyte disturbances. **Reproductive system and breast disorders:** **Uncommon:** Inflammation and ulceration of the vagina. **Very rare:** Loss of libido, impotence, gynaecomastia, oligospermia, impaired menstruation, vaginal discharge. **Musculoskeletal and connective tissue disorders:** uncommon: Arthralgia, myalgia, osteoporosis. **Neoplasms benign malignant and unspecified (incl. cysts and polyps):** Very rare: Reports of individual cases of lymphoma which subsided in a number of cases once treatment with methotrexate had been discontinued. **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 GmbH, Theaterstraße 2/280 Wedel, Germany. **Marketing authorisation number:** PA 623/14/1. **Date of Revision of PI:** February 2017. **MARKETED IN IRELAND BY:** FANNIN LTD, FANNIN HOUSE, LEOPARDSTOWN, DUBLIN 18.

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 868394447 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 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie REF: IE17/05/SmPC - APR2015

Irish Society for Rheumatology



Autumn Meeting 2017

**taking place
21-22 September
in the
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Efficacy still going strong five years on

monthly
Simponi[®]
golimumab



Indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients in combination with MTX when response to DMARDs therapy, including MTX, has been inadequate.



Indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to DMARDs has been inadequate.



Indicated for the treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.

**SIMPONI 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
SIMPONI 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (GOLIMUMAB)**
Prescribing Information (Refer to full SPC text before prescribing Simponi (golimumab))

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-AS): Simponi is indicated for the treatment of severe, active nr-AS in adults 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 5-mercaptopurine (5-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **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-AS or UC. 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-AS: 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, then 50 mg every 4 weeks. 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). 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) and patients

with renal and hepatic impairment: Simponi is not recommended in these populations. **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 Alert 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 (all TNF-blocking agents including Simponi) and Merkel cell carcinoma (other TNF-blocking agents) 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,

The GO studies

Recently presented five-year data confirm good persistence, sustained efficacy and predictable tolerability across indications with Simponi¹⁻³

Persistence with
Simponi at 5 years

(Simponi 50mg and 100mg)



GO-FORWARD¹

70%

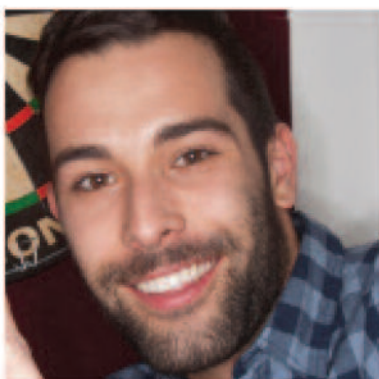
n=444



GO-REVEAL²

69%

n=405



GO-RAISE³

71%

n=356

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 therapy 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, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers. Cytopenias including pancytopenia have been reported infrequently in clinical trials. 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:** 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. **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, 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, thrombocytopenia, pancytopenia, aplastic anaemia, 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, but not

observed in clinical studies with golimumab. **Package quantities:** 1 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection or 1 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection or 1 100 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:** December 2015. **Further information is available on request from:** MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. **Date of preparation:** March 2016.

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: 01-299 8700)

References

1. Keystone EC, et al. J Rheumatol. 2016 Feb;43(2):298-306.
2. Kavanaugh A, et al. Ann Rheum Dis. 2014 Sep;73(9):1889-94.
3. Deodhar A, et al. Ann Rheum Dis. 2015 Apr;74(4):757-61.



Red Oak North, South County Business Park,
Leopardstown, Dublin 18 X5K7 Ireland





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More than
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More than
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publications¹⁹

1 Over
million
patients
treated¹⁰

of partnership and experience¹
over
15
years



ABBREVIATED PRESCRIBING INFORMATION

Enbrel[®] etanercept

Before prescribing Enbrel[®] please refer to full Summary of Product Characteristics (SmPC). **Presentation:** Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC[®]): Enbrel 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. Non-radiographic axial spondyloarthritis (nr-axSpA). Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). Children aged 2-17 years: Juvenile idiopathic arthritis (JIA). Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesitis-related arthritis from the age of 12 years when inadequate response to, or intolerant of, conventional therapy. Children aged 6-17 years: Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** By subcutaneous injection. Adults: RA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS, nr-axSpA and PsA – 25 mg twice weekly or 50 mg once weekly. Children aged 2-17 years: JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. Children aged 6-17 years: Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure (CHF). There have been rare (< 0.1%) reports of new onset CHF, including CHF in patients without known preexisting cardiovascular disease, including patients under 50 years of age. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients previously infected with hepatitis B and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy ≤ 18 years of age) in the post marketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have been reported very infrequently in patients treated with Enbrel. Periodic skin

examination is recommended for all patients, particularly those with risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and lifethreatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, heart failure, autoimmune hepatitis, Steven Johnson's syndrome, anaphylaxis, and very rare reports of: toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post-operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. See section 4.8 of the SmPC for how to report adverse reactions. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC): Each carton contains 4 pre-filled pens containing 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **Legal Category:** S1A.

European Marketing Authorisation Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. **For full prescribing information see the Summary of Product Characteristics. 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. **API Reference Number:** EN 9_0 Pfilet number: 2015-0011787, 2015-0011936, 2016-0015782. **Date of Prescribing Information:** April 2016.

[†] Across all indications.

References: 1. Scott LJ. Drugs. 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. 3. Humira Summary of Product Characteristics. 4. Remicade Summary of Product Characteristics. 5. Cimzia Summary of Product Characteristics. 6. Simponi Summary of Product Characteristics. 7. Remicade EMA report 8. www.clinicaltrials.gov. Date accessed: May 2016. 9. <http://www.ncbi.nlm.nih.gov/pubmed>. Date accessed: May 2016. 10. Data on File. January 2015. 11. Data on File, February 2016.

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THINK RoACTEMRA¹

IN DMARD-IR AND TNF-IR RA PATIENTS,
WHEN COMBINATION WITH MTX IS NOT AN OPTION

ABRIDGED PRESCRIBING INFORMATION (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). **RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC).** **Indications:** **RoActemra SC:** 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 adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. **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/SC** 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. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. Assess suitability of patient for subcutaneous home use and instruct patient to inform HCP if they experience symptoms of an allergic reaction before administering the next dose. Limited data available regarding switching patients from RoActemra IV to RoActemra SC. **RA: RoActemra IV:** 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients >100 kg, doses >800 mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Alternate injection site frequently. **sJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients ≥ 2 years, 8mg/kg diluted to final volume of 100ml for patients ≥ 30 kg or 12mg/kg diluted to final volume of 50ml for patients <30 kg 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 <30 kg 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. **Dose adjustments:** For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or 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 $2 \times 10^9/L$. **Special Populations:** No data available for RoActemra SC in patients <18 years of age. Closely monitor renal function in patients with moderate to 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. **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, associated with 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. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. 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. 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 $> 5 \times \text{ULN}$; caution in patients with ALT or AST $> 1.5 \times \text{ULN}$ (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 $< 0.5 \times 10^9/L$ or platelet count $< 50 \times 10^9/L$. Do not initiate RoActemra treatment where ANC is below $2 \times 10^9/L$. Caution in patients with low platelet count; monitor neutrophils and platelets in RA, 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 should be clearly recorded in patient file to improve traceability of biological medicines. **Drug 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 must use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-fetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. No lactation data in humans. 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. 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:** ADRs occurring in RoActemra trials: **Very Common** ($\geq 1/10$): upper respiratory tract infections, hypercholesterolaemia. **Common** ($\geq 1/100 - <1/10$): 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, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. **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** ($\geq 1/10$): upper respiratory tract infections, nasopharyngitis, decrease in neutrophil count. **Common** ($\geq 1/100 - <1/10$): 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** ($\geq 1/10$): upper respiratory tract infections, nasopharyngitis, headache. **Common** ($\geq 1/100 - <1/10$): nausea, diarrhoea, infusion related reactions, hepatic transaminases increased, decrease in neutrophil count. **RoActemra SC:** 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. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), PI 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). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. 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 Preparation:** August 2016. **Reference:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. Int. J. Clin. Rheumatol. (2012) 7(1): 9-19. **Date of item:** September 2016. IE/RACTE/0916/0020



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