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# Irish Society for Rheumatology Spring Meeting 2014



21 March, 2014  
Radisson Blu Hotel  
Athlone

Brochure kindly sponsored by MSD







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

THINK  
ROACTEMRA<sup>1</sup>

 **RoACTEMRA**<sup>®</sup>  
tocilizumab

RoACTEMRA, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, RoACTEMRA can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoACTEMRA 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 methotrexate.<sup>2</sup>

**ABRIDGED PRESCRIBING INFORMATION. (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). RoActemra® (Tocilizumab) 20mg/ml Concentrate for Solution for Infusion**

**Indications:** (i) In combination with methotrexate (MTX), for the treatment of adult patients with moderate to severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists. In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoActemra 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 methotrexate. (ii) As monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX, for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients > 2 years of age, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. (iii) In combination with MTX, for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients > 2 years of age, who have responded inadequately to previous therapy with MTX. In these patients RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. **Dosage and Administration:** Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. **RA Patients:** Recommended posology is 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by iv infusion over 1 hour. For patients weighing > 100kg, doses > 800mg per infusion are not recommended. No data on doses above 1.2g. **Dose adjustments:** Dose modification, interruption or in some cases discontinuation of RoActemra recommended in the event of raised liver enzymes, low absolute neutrophil count (ANC) or low platelet count (see SmPC for details). In patients not previously treated with RoActemra, initiation not recommended in patients with an ANC below  $2 \times 10^9/l$ . Closely monitor renal function in patients with moderate to severe renal impairment as RoActemra has not been studied in these patients. No data in patients with hepatic impairment. **sJIA Patients:** No data in patients < 2 years of age. **Posology:** In patients > 2 years of age - 8mg/kg diluted to a final volume of 100ml for patients > 30kg or 10 mg/kg diluted to a final volume of 50ml for patients < 30kg once every 2 weeks by iv infusion over 1 hour. Check patient's weight at each visit - refer to SmPC. In the event of raised liver enzymes, low ANC or low platelet count, interrupt/discontinue RoActemra dose or modify/stop concomitant MTX and other medications where appropriate - see SmPC for details. Reduction of RoActemra dose due to laboratory abnormalities not studied in sJIA patients. Clinical improvement is generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement is seen in this timeframe. **pJIA Patients:** No data in patients < 2 years of age. **Posology:** In patients > 2 years of age - 8mg/kg diluted to a final volume of 100ml for patients > 30kg or 10 mg/kg diluted to a final volume of 50ml for patients < 30kg once every 4 weeks by iv infusion over 1 hour. Check patient's weight at each visit - refer to SmPC. In the event of raised liver enzymes, low ANC or low platelet count, interrupt/discontinue RoActemra dose or modify/stop concomitant MTX and other medications where appropriate - see SmPC for details. Reduction of RoActemra dose due to laboratory abnormalities not studied in pJIA patients. Clinical improvement is generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement is seen in this timeframe. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Warnings and Precautions:** Serious (sometimes fatal) infections reported in patients receiving immunosuppressive agents including RoActemra. Do not initiate in patients with active infection. If serious infection develops interrupt therapy until infection controlled. Caution in patients with history of recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which may predispose patients to infection. Vigilance for the timely detection of serious infection recommended. Advise all patients and parents/guardians of sJIA and pJIA patients to contact their healthcare professional immediately when symptoms suggestive of an infection appear. Screen for latent TB prior to starting therapy. Treat latent TB with standard antimicrobial therapy before initiating RoActemra. Risk of false negative tuberculin skin and interferon-gamma TB blood test results, especially in severely immunocompromised patients. Advise patients to seek medical attention if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever) suggestive of TB infection occur during or after treatment with RoActemra. Viral reactivation (e.g. hepatitis B) reported with biologic therapies for RA. Patients screening positive for hepatitis excluded from clinical trials. Events of diverticular perforations as complications of diverticulitis reported uncommonly with RoActemra in RA patients. Exercise caution in patients with a history of intestinal ulceration or diverticulitis. Evaluate patients with symptoms of complicated diverticulitis promptly. Serious hypersensitivity reactions reported - may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous infusions 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 with RoActemra. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, stop administration of RoActemra immediately and discontinue therapy permanently. Use with caution in patients with active hepatic disease or hepatic impairment. Not recommended in patients with baseline ALT or AST > 5 x ULN; use with caution in patients with ALT or AST > 1.5 x ULN. Monitor ALT and AST levels for RA, sJIA and pJIA patients according to SmPC - other liver function tests including bilirubin should be considered where indicated. If raised, follow dosage recommendations in SmPC for RA, sJIA and pJIA patients. Risk of neutropenia may be increased in patients previously treated with a TNF antagonist. Continued therapy not recommended in patients who develop an ANC <  $0.5 \times 10^9/l$  or platelet count <  $50 \times 10^9/l$ . In patients not previously treated with RoActemra, initiation not recommended 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. If reduced, follow dosage recommendations in SmPC for RA, sJIA and pJIA patients. Elevations in lipid parameters seen - refer to SmPC. Assess lipid parameters according to SmPC if elevated; manage patients according to local guidelines for hyperlipidaemia. Potential for central demyelination with RoActemra currently unknown; physicians should be vigilant for symptoms of new onset disease. Immunomodulatory medicines may increase malignancy risk in RA patients. Do not give live and attenuated vaccines concurrently with RoActemra as safety not established - refer to SmPC for further details on immunisations. RA patients should have CV risk factors managed as part of usual standard of care. Not recommended for use with other biological agents. Macrophage activation syndrome (MAS) is a serious life-threatening disorder that may develop in sJIA patients - RoActemra has not been studied in patients during an active MAS episode. Advise patients experiencing dizziness not to drive or use machines until dizziness resolved. Product contains 26.55mg sodium per 1200mg. **Drug Interactions:** Interaction studies only performed in adults. In RA patients, levels of simvastatin (CYP3A4) were decreased by 57% one week following a single dose of tocilizumab to levels similar to or slightly higher than those observed in healthy subjects. Monitor patients taking medicines which are individually adjusted and metabolised by CYP450 3A4, 1A2 or 2C9 when starting or stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. The effect of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy. Refer to SmPC for further details on the effects of RoActemra on cytochrome CYP450 and drug interactions generally. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use effective contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed an 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). **Side Effects and Adverse Reactions:** RA: Most commonly reported ADRs (occurring in > 5% patients treated with tocilizumab monotherapy or with DMARDs) were upper respiratory tract infections, nasopharyngitis, headache, hypertension and increased ALTs. ADRs occurring in patients with RA receiving tocilizumab as monotherapy or in combination with MTX or other DMARDs in the clinical trial double-blind controlled periods. Very Common (> 1/10): upper respiratory tract infections and hypercholesterolaemia. Common (> 1/100 - < 1/10): cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. sJIA: In general, the ADRs were similar to those seen in RA patients. **Infections** - Serious infections of varicella and otitis media reported, in addition to infections for RA. **Infusion reactions** - Hypersensitivity reactions requiring treatment discontinuation occurred in < 1% of patients. Other events occurring within 24 hours of infusion in 16% of patients included, but were not limited to rash, urticaria (considered serious), diarrhoea, epigastric discomfort, arthralgia and headache. IgG - decreased levels during therapy. **Other** - decreases in neutrophil and platelet counts, hepatic transaminase elevations, lipid parameter increases and anti-tocilizumab antibodies observed. **Serious or Potentially Serious:** serious infections, active pericarditis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), gastrointestinal perforations (as complications of diverticulitis), serious hypersensitivity reactions. pJIA: In general, the ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count were more frequently reported in the pJIA population and increased cholesterol was less frequently reported in pJIA than RA. **Infections** - The incidence of infections leading to dose interruptions was numerically higher in patients weighing < 30 kg, the rate of serious infections was also higher in these patients. **Infusion reactions** - 20.2% experienced an event within 24 hours of infusion. No clinically significant hypersensitivity reactions associated with tocilizumab and requiring treatment discontinuation were reported. Refer to SmPC for a complete listing of adverse events for RA, sJIA and pJIA. See SmPC section 4.8 for instructions on the reporting of Suspected Adverse Reactions. **Legal Category:** Product subject to medical prescription which may not be renewed (A). **Presentations and 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). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information available from Roche Products (Ireland) Limited, 3000 Lakes Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** November 2013. Copyright © 2013 by Roche Products (Ireland) Ltd. All rights reserved. **References:** 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. 2. SmPC. RoACTEMRA (tocilizumab) Summary of Product Characteristics, 25 September 2013. **Date of Item:** December 2013. p03/12/13.





## WELCOME

### Dear Colleagues and Friends

It is my great pleasure as President of ISR to welcome you to the 2014 ISR Spring Meeting in the Radisson Blu Hotel in Athlone. I am honoured to wear this chain of office which has been worn with great distinction by Rheumatologists of great renown over the past forty years. If you haven't done so already I hope you will find the time to complete the ISR members survey which will help the Society in understanding what you want from the ISR in the future. I would also like to hear your opinions on some new developments the ISR plans over the next two years.

On behalf of the ISR I would like to thank the Academic Organisers, Dr Killian O'Rourke, Dr Chifan Cheuk, Dr Ausuf Mohammad and Dr Sandra Busteed all from the Midlands Hospitals for their efforts in putting together such an excellent programme.

I look forward to welcoming all of our speakers. Mr David Borton will update us on "Orthopaedic Foot Surgery", complemented by Mr Philip Grieve from Blackrock Clinic who will discuss Hand surgery advances. We welcome back Professor David Isenberg who will undoubtedly give a stimulating lecture on SLE – origins & outcomes and Mike Cummings from the British Medical Acupuncture Society (BMAS) will talk on the Evidence for acupuncture for the treatment of knee osteoarthritis`

The programme range is broad and interesting and I look forward to meeting the expert presenters some of whom will be presenting at ISR for the first time.

I would especially like to thank our pharmaceutical industry colleagues for their continued support of this meeting, and I would ask you to show your appreciation by visiting the stands.

We seem to be nearing the end of an extremely difficult period of severe cutbacks in the health services in Ireland and now face into a future model of healthcare that has yet to be defined to any of us. At times like this the ISR is more important than ever in representing our specialty and in making a strong case for appropriate funding for our services and patients. I hope that we can work together on this and continue to grow our specialty. The future of our specialty will depend on attracting high quality candidates to our training scheme and I hope to develop innovations for undergraduates and NCHDs in order to raise the profile of Rheumatology as an interesting and fulfilling career choice.

I hope that you all enjoy the meeting and I look forward to meeting with many of you in the course of the day.

**Professor David Kane,**  
ISR President



# HUMIRA

adalimumab

10  
YEARS

THE POWER TO FIGHT AXIAL SPA\*



**\*Axial Spondyloarthritis**

**Ankylosing spondylitis**

HUMIRA is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

**Axial spondyloarthritis without radiographic evidence of AS**

HUMIRA is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.<sup>1</sup>

**Rheumatoid arthritis**

HUMIRA in combination with methotrexate, is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.<sup>1</sup>

Full prescribing information is available upon request from AbbVie Limited, Block B, Liffey Valley Office Campus, Quarryvale, Co Dublin, Ireland. **Legal category** POM. **Marketing Authorisation Numbers:** EU/1/03/256/001-005, EU/1/03/256/007-010. **Marketing Authorisation Holder:** AbbVie Ltd., Maidenhead, Berkshire SL6 4XE, UK.

**Reference: 1.** For more information on HUMIRA's licensed indications, please refer to Humira's Summary of Product Characteristics available on [www.medicines.ie](http://www.medicines.ie).

IREHUR130278

**Date of Preparation:** September 2013

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## PROGRAMME ISR Spring Meeting

### Friday 21st March 2014, Radisson Blu Hotel, Athlone

#### Thursday 20th March 2014

7.30p.m. **Drinks Reception**

8.00p.m. **Dinner**

#### Friday 21st March 2014

09.30a.m. **Registration**  
Coffee and Meeting the Industry

#### Morning Session

9.55a.m. **Opening Address**  
Prof David Kane, President ISR

Chairs: Dr Ausaf Mohammad and Dr Killian O'Rourke

10.00a.m. Mr David Borton  
Consultant Orthopaedic Surgeon, Hermitage Medical Clinic, Dublin  
**Title: 'Foot orthopaedic surgery'**

11.00a.m. Dr Harsha Gunawardena  
Consultant Rheumatologist, North Bristol NHS Trust  
**Title: 'The spectrum of myositis – clinical-serological syndromes'**

12.00 p.m. Professor David Isenberg  
ACR Diamond Jubilee Professor of Rheumatology, UCH London  
**Title: 'SLE - Origins and Outcomes'**

13.00p.m. **Lunch & Meeting the Industry**

#### Afternoon Session

Chairs: Dr Chifan Cheuk and Dr Sandra Busteed

14.15p.m. Mr Philip Grieve  
Consultant Orthopaedic Surgeon, Blackrock Clinic, Dublin  
**Title: 'An Update on Hand & Wrist Surgery'**

15.15p.m. Dr Mike Cummings  
Medical Acupuncturist and Medical Director of the  
British Medical Acupuncture Society (BMAS)  
**Title: 'Evidence for acupuncture for the treatment of knee osteoarthritis'**

16.15p.m. **Coffee Break & Meeting the Industry**

16.30 Patricia Minnock  
**IRNF Proposal: Developing Clinical Nurse Specialists and  
Advanced Nurse Practitioners Posts Together**

# Help put everyday life back in their hands

## Efficacy still going strong five years on



### The GO studies

Five-year data confirm good persistence, sustained efficacy and predictable tolerability with Simponi in RA, AS and PsA<sup>1-4</sup>

**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. **Ankylosing Spondylitis (AS):** Simponi is indicated for treatment of severe, active AS in adults who have responded inadequately to conventional therapy. **Ulcerative colitis (UC):** Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **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 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:** 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. **Elderly 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. 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) and discontinued in the event of worsening symptoms of heart failure. **Neurological events:** Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. **Surgery:** Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. **Haematological reactions:** There have been post-marketing reports of pancytopenia, leucopenia, 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. 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 are 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, viral infections, bronchitis, sinusitis, superficial fungal infections, anaemia, allergic reactions, autoantibody positive, dizziness, headache, hypertension, dyspepsia, gastrointestinal and abdominal pain, nausea, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, pyrexia, asthenia and injection site reaction, were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma\*, hepatosplenic T-cell lymphoma\*, leucopenia, 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:** 150 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection or 150 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection or 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 © Merck Sharp & Dohme Ireland (Human Health) Limited, 2013. All rights reserved. **Date of Revision of Text:** October 2013. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). **Date of preparation:** December 2013.

#### References:

1. Keystone E et al. Presented at EULAR 2013 Congress, Madrid, Spain, June 12-15, 2013. Abstract AB0267.
2. Han C et al. Presented at EULAR 2013 Congress, Madrid, Spain, June 12-15, 2013. Abstract THU0513.
3. Kavanaugh A et al. Presented at EULAR 2013 Congress, Madrid, Spain, June 12-15, 2013. Abstract AT0270.
4. Deodhar A et al. Presented at EULAR 2013 Congress, Madrid, Spain, June 12-15, 2013. Abstract THU0352.



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





## Academic Organisers

### Dr Killian O'Rourke

Dr Killian O'Rourke graduated from Queens University Belfast in 1996 and subsequently completed his MSc and MD in University College Cork. He was awarded CCST in Rheumatology and General Medicine in 2005 after completion of higher specialist training in Bristol Royal Infirmary. He was appointed as Locum Consultant Rheumatologist in Bristol Royal Infirmary in 2005, before taking up a substantive position as Consultant Rheumatologist and General Physician in Taunton and Somerset NHS Trust in 2006. He was appointed as Consultant Rheumatologist and General Physician at the Midlands Regional Hospital, at Tullamore in 2009.



### Dr Chifan Cheuk

Chifan is a graduate of Queens University Belfast, and has trained in the Belfast City Hospital, The Royal Victoria Hospital and Musgrave Park before accepting the SPR rheumatology training in Ireland; she completed the rheumatology and GIM training in 2005. Chifan completed a Masters in Sports and Exercise Medicine in UCC in 2003. Chifan has a special interest in Western medicine acupuncture and is a member of the British medical Acupuncture Society. Chifan currently works as a consultant rheumatologist in the Bon Secours Hospital, Tralee and in St Francis Hospital, Mullingar.



### Dr Sandra Busteed

MD MRCP

Dr. Sandra Busteed is a Consultant Rheumatologist at St. Francis Hospital, Mullingar. After graduating from University College Cork, she completed initial training in Cork University Hospital. She began her specialist training in Cork and undertook research in the Dept. of Medicine, leading to an MD. She completed her specialist training in the Mersey Deanery, Liverpool where she trained in University Hospital Aintree and the Royal Liverpool University Hospital. Her areas of interest are inflammatory arthritis and PMR.



### Dr Ausaf Mohammad

Dr. Ausaf Mohammad qualified from Pakistan in 1999, graduating with honours. He completed the Irish SpR training in Rheumatology and General Medicine in July 2013. He completed MSc in Clinical Research and Epidemiology from the National University of Ireland (NUI), Galway and McMaster



University Canada in June 2012. He plans to submit MD to NUI Galway on Arterial Calcification and Cardiovascular Disease in Rheumatoid Arthritis. He commenced a permanent substantive position as a full time Consultant Rheumatologist and General physician in Midland Regional Hospital, at Tullamore as of July 2013. He has a keen interest in a number of sports, particularly cricket and Golf.

## Speakers

### Mr David Borton

Consultant Orthopaedic Surgeon -  
Hermitage Medical Clinic



#### Specialities:

- Foot and Ankle Surgery
- Hip Replacements
- Knee Replacements/Reconstructions

#### Experience:

- BA, MB, B.CH, BAO Trinity College
- FRSCI November 1990
- M.Ch August 1995
- FRCS (Orth) 1995
- Foot and Ankle Fellowship – Brisbane, Australia 1996
- Knee and Joint Replacement Fellowship – Sydney, Australia 1997
- Awarded EFFORT travelling fellowship 1996

#### Orthopaedic Associations:

- Member of Irish Orthopaedic Association
- Member of Irish Orthopaedic Foot and Ankle Society
- Member of American Orthopaedic Foot and Ankle Society
- Member of European Foot and Ankle Society

### Dr Harsha Gunawardena

MRCP(UK), PhD

Practising at: Spire Bristol Hospital Qualified from Bristol University, and then worked in Bristol and Australia. Trained in Rheumatology and General Medicine on the Southwest training rotation.



Undertook a clinical research fellowship under the mentorship of Professor Neil McHugh at the Royal National Hospital of Rheumatic Diseases in Bath and was subsequently awarded an Arthritis Research UK Research Fellowship in Paediatric Rheumatology to research immunological aspects of juvenile dermatomyositis with the UK Juvenile Myositis Research Group. Dr Gunawardena's PhD thesis was "Clinical and serological study of adult and juvenile myositis".

He continues to have a major academic interest in connective tissue disease and myositis. He sits on the UK Myositis Network Steering committee, scientific advisor to the UK Juvenile Myositis Research Group, in addition to other UK connective tissue disease study groups. He is widely published in major international rheumatology journals, and has written several invited myositis review articles. He has spoken at several international meetings



# WORKING ON A CURE

You are cordially invited to this special lecture of  
**Prof. Gerry Wilson, Arthritis Ireland  
Chair of Rheumatology**

Discussion:

**Plans for life-changing research  
in rheumatology in Ireland**

**Where:** Rochestown Park Hotel, Douglas, Co. Cork

**When:** Wednesday, 26th March 7:30pm

**Register:** Admission is Free. Booking is Essential.

**Online:** [arthritisireland.ie](http://arthritisireland.ie) Call: 1890 252 846



**Arthritis Ireland**

Little Things make a Big Difference



*"When I was diagnosed with arthritis the outlook was bleak but Arthritis Ireland supporting research today gives me hope for a brighter, pain-free future."*

**June Hendrick**

## LIVING WELL WITH ARTHRITIS

### Arthritis Self-Management Programme

**Make it part of the prescription for  
your patients**

By complementing clinical treatment with education and training, self-management enables and empowers patients to live happier and healthier lives and results in major savings to the healthcare system.

By referring your arthritis patients to our Living Well with Arthritis self-management programme you will be helping them discover how they can play an active role in the management of their condition.

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*"Enabling patients to be more independent, knowledgeable and ultimately healthier, and therefore less reliant on health service support is a key objective of self-management education tools."*

**Dr. Áine Carroll, National Director for Clinical  
Strategy and Programmes, HSE**





including the American College of Rheumatology Annual Congress (2010) and the European Science Foundation Myositis Workshop (2011).

As a NHS Consultant He runs both General Rheumatology and Autoimmune Connective Tissue Disease Clinics at North Bristol NHS Trust. He also looks after patients with all forms of inflammatory arthritis including rheumatoid arthritis, and is the lead Consultant for Connective Tissue Disease and Vasculitis for the Rheumatology Department, and is fully experienced in using novel immunomodulatory treatments including biologic therapy for these complex conditions.

### Prof David Isenberg

MD, FRCP, FAMS

Professor Isenberg is the Arthritis Research UK Diamond Jubilee Professor of Rheumatology, University College London Medical School, UK. He graduated from the University of London in 1973, after which he pursued his clinical training at University College Hospital (UCH), London. He undertook the Jules Thorn Scholarship in Rheumatology & Haematology in UCH, after which he became a Research Fellow in Haematology / Oncology at Tufts University, Boston, USA. He returned to the UK in 1983 as a Senior Registrar in Rheumatology at UCH and shortly afterwards was offered a Consultant Rheumatologist post. He has been Professor of Rheumatology since 1992. He has an extensive publication record and has been honoured on multiple occasions for his research in SLE and other rheumatic diseases. He received the Evelyn Hess prize award in 2010 from The Lupus Foundation of America for 'outstanding contribution to research and treatment of Lupus'. He was awarded the Roger Demers award in 2012 from the Laurentian Conference of Rheumatology for 'Unique Contribution to International Rheumatology'.



### Mr Philip Grieve

FRCSed (Tr & Orth)

Consultant Orthopaedic Trauma & Hand and Wrist Surgeon

Philip is a Consultant Orthopaedic Trauma and Hand & Wrist Surgeon in Blackrock Clinic in Dublin and with 3fivetwo Healthcare in Belfast, Northern Ireland. Whilst he is a Queen's graduate originally, he left Northern Ireland to obtain experience in New Zealand prior to undergoing his Higher Surgical Training in Trauma & Orthopaedic Surgery in London. Following a fellowship in Hand and Wrist Surgery in London, a Poly-trauma fellowship in Adelaide South Australia and an Orthopaedic & Trauma fellowship in New Zealand he came to Dublin in 2011 to a temporary position at St James's/AMNCH. He took the opportunity to embark on full-time private practice at Blackrock Clinic knowing that he had a niche interest in Orthopaedic Hand and Wrist surgery with an emphasis on complex wrist surgery. He offers the most up-to-date treatment options for hand and wrist complaints including wrist



arthroscopy and small joint arthroscopy, minimally invasive approaches to fracture fixation (e.g. percutaneous scaphoid fixation) and endoscopic nerve releases to name but a few. His fracture practice focuses on early mobilisation protocols and maximising function. Philip is a dedicated and passionate person who strives for excellence in all that he does. Whilst demanding high standards he is down-to-earth and approachable in his manner. He takes pride in his caring attitude and straightforward style. He lives in Dublin with his (Kiwi) wife and three children.

### Dr Mike Cummings

Mike Cummings qualified in medicine from Leeds University in 1987 and joined the RAF as the military equivalent of a GP. Much of his experience there was in treating sports/physical activity related injury and he continues to be interested in musculoskeletal medicine. It was also in the RAF that he began to use acupuncture, having taken a foundation course run by the British Medical Acupuncture Society (BMAS). Subsequently he taught on BMAS training courses, becoming Director of Education for BMAS in 1997, and then Medical Director in 2001.

He lectures and teaches in the UK and internationally, and has been a member of the NICE Low Back Pain Guideline Development Group, DH (England) Steering Group for the Statutory Regulation of acupuncture, and DH (England) Acupuncture Regulation Working Group, amongst others.

He has been a reviewer for acupuncture papers in numerous journals including Annals of Internal Medicine and the BMJ, and contributed to systematic reviews into acupuncture, as well as being a Cochrane Reviewer. He was Editor of Acupuncture in Medicine (Medline listed, published by the BMJ Group) for eight years and has been Associate Editor since 2009. He is a Director At Large of ICMART, the International Council of Medical Acupuncture and Related Techniques.



### ISR Board members

#### 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





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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 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.

### Dr Suzanne Donnelly



Dr Suzanne Donnelly graduated from Trinity College Dublin, trained in Ireland and England and was appointed consultant rheumatologist at St. George's Hospital and Medical School, London in 2002. She returned to Ireland in 2005 to work part time as Consultant Rheumatologist in the Mater Misericordiae University Hospital. Her clinical and educational research interests include systemic autoimmune disease, Systemic Lupus Erythematosus and Care in Medicine. Suzanne has held academic posts in medical education since 1996 including in Trinity College Dublin; the University of Oxford and in London, and joined UCD as Director of Clinical Education in 2008, to lead the development of early clinical education. She was responsible for a series of innovative educational strategies across

all disciplines including the development of a patient educator programme in association with Arthritis Ireland. She led the first national undergraduate curriculum project in Ireland, published as the ISR Undergraduate Curriculum in Rheumatology in 2009, and is a contributing author to the textbooks *Medicine at A Glance* & *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 is a medical patron of Lupus Group Ireland.

### Dr Sandy Fraser



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.

### Dr Donough Howard



Donough Howard is a Consultant Rheumatologist at St James's Hospital and Hermitage Medical Clinic. Dr Howard is the national specialty director for rheumatology. He graduated from RCSI and completed postgraduate training both in Ireland and the US. He previously worked in Lahey Clinic Medical Centre, with academic appointments to both Harvard and Tufts Medical Schools. Dr Howard has published in the fields of vasculitis and also has subspecialty interests in the fields of scleroderma.

### Dr Miriam O'Sullivan





Over 20 years  
and 3 million  
patient-years  
collective  
clinical  
experience<sup>9,10</sup>

# The ENBREL way

Indicated for RA, PsA, JIA, AS and PsO<sup>#</sup>

## A unique mechanism of action

- Enbrel is the only fully human soluble tumour necrosis factor (TNF) receptor<sup>1,2,3,4,5,6</sup>
- It works differently than MAB's<sup>1</sup>

## No neutralising antibodies<sup>1</sup>

- Enbrel is not associated with the production of neutralising antibodies in humans

## Enbrel has a short half life (<3 days)<sup>1</sup>

- The half-life of anti-TNF agents should be taken into account if a treatment break is required<sup>1</sup>

## Efficacy

- Registry data and Cochrane Review data support efficacy & safety of Enbrel<sup>7,8</sup>

### Enbrel (etanercept) Abbreviated Prescribing Information

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 (PsA) 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. 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 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. 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 identified as carriers of hepatitis B virus 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 postmarketing 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 antidiabetic 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 breastfeeding 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 life threatening 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, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) has 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 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. Legal Category: POM. 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. S1B: Product subject to a prescription which may be renewed. 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 363 633 or at [EJMEDINFO@pfizer.com](mailto:EJMEDINFO@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\_6\_1. Date of Prescribing Information: December 2012.

#### References:

1. Enbrel Summary of Product Characteristics August 2013.
2. Remicade Summary of Product Characteristics.
3. Humira Summary of Product Characteristics.
4. Ocrencia Summary of Product Characteristics.
5. Mabthera Summary of Product Characteristics.
6. Simponi Summary of Product Characteristics.
7. Singh J et al. CMAJ:2009 DOI:10.1503.
8. Hettland ML et al. Arthritis & Rheumatism. Vol 62, no 1, January 2010.
9. Data on File Pfizer Inc. 10 Data on File Amgen

# Rheumatoid Arthritis, Psoriatic Arthritis, Juvenile Idiopathic Arthritis, Ankylosing Spondylitis and Psoriasis. For full prescribing information see the Summary of Product Characteristics.

ENB/2013/192/1  
Date of preparation: September 2013







Miriam O Sullivan is a final year SpR working in Galway University and Merlin Park Hospitals. She is participating in the flexible training scheme for SpRs funded by the medical education and training office.



### Dr Gary Wright

Dr Wright qualified from Queens University in 1987 and was appointed Consultant Rheumatologist at the Royal Victoria Hospital and Musgrave Park Hospitals in Belfast in 1998. He is an Honorary Clinical lecturer at Queen's University Belfast. He trained in Rheumatology in Belfast and spent a further year as Honorary Senior Registrar in Nottingham with Professor Mike Doherty. His Research interests include the genetics of osteoarthritis and crystal disease, early diagnosis and treatment of inflammatory arthritis and musculoskeletal ultrasound in rheumatic disorders.



### recently joined the board:

**Dr Clare Matthews**

**Dr Eamonn Molloy**

**Dr Adrian Pendleton**

## ISR AUTUMN 2014

at

**Fitzpatrick Castle Hotel,  
Killiney (Co.Dublin)**

**Thursday 11th & Friday 12th  
September 2014**

## ISR Presidents

**Prof D. Kane** 2014 – Present  
Dublin

**Dr G. Wright** 2012 - 2014  
Belfast

**Prof. G. Cunnane** 2010 – 2012  
Dublin

**Dr. R. Kavanagh** 2008-2010  
Galway

**Dr. J. Lee** 2006-2008  
Craigavon

**Dr. P. O'Connell** 2004-2006  
Dublin

**Prof. O. Fitzgerald** 2002-2004  
Dublin

**Dr. A. Taggart** 2000-2002  
Belfast

**Dr. D. Raman** 1998-2000  
Sligo

**Dr. A. Bell** 1996-1998  
Belfast

**Prof. B. Bresnihan** 1994-1996  
Dublin

**Prof. M. Molloy** 1992-1994  
Cork

**Dr. E. Casey** 1990-1992  
Dublin

**Dr. S. Roberts** 1988-1990  
Belfast

**Dr. C. Barry** 1985-1987  
Dublin

**Dr. D. Roden** 1983-1985  
Dublin

**Dr. W. Boyd** 1981-1983  
Belfast

**Dr. T. Gregg** 1979-1981  
Dublin

**Dr. J. Molony** 1977-1979  
Dublin

**Dr. M. McMahon** 1975-1977  
Cork

**Dr. T. O'Reilly** 1973-1975  
Dublin



# Connecting with **patients**

"I would like to change the perception of rheumatoid arthritis and increase public awareness. It is associated with the elderly, but it is a disease that can happen to anyone at any age. I'm grateful for the therapies that are available now to help sufferers live their lives as best they can."

**Alison**, living with rheumatoid arthritis

UCB has a passionate, long-term commitment to help patients and families living with severe diseases lead normal, everyday lives.

Our ambition is to offer them innovative new medicines and ground-breaking solutions in two main therapeutic areas: neurology and immunology. We foster cutting-edge scientific research that is guided by patients' needs.



## DAY 1: CLINICAL ORAL PRESENTATIONS AUTUMN 2013



Dr Elisabeth Ball



Dr Len Harty



Dr Eimear Savage



Dr Claire Louise Murphy

## DAY 2: CLINICAL CASE ORAL PRESENTATIONS AUTUMN 2013



Dr Claire Benson



Dr Ali Taha



Dr Kieran Murray



Dr Surabhi Waghmare





# ARCOXIA®

etoricoxib

## DEMONSTRATED POWERFUL PAIN RELIEF<sup>1,a</sup>



### For the symptomatic relief of<sup>1</sup>

**Osteoarthritis<sup>b</sup>** **30-60mg**  
once daily

**Rheumatoid Arthritis** **90mg**  
once daily

**Ankylosing Spondylitis** **90mg**  
once daily

### For the short-term treatment of<sup>1</sup>

**Postoperative Moderate Dental Surgery Pain** **90mg**  
once daily,  
maximum 3 days.

**Acute Gouty Arthritis** **120mg**  
once daily,  
maximum 8 days.

**ARCOXIA® (etoricoxib) ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing. **PRES-ENTATION** Tablets: 30mg, 60 mg, 90 mg and 120 mg tablets each containing 30mg, 60 mg, 90 mg or 120 mg of etoricoxib respectively. **INDICATIONS** Symptomatic relief of osteoarthritis, rheumatoid arthritis (RA), ankylosing spondylitis (AS) and the pain and signs of inflammation associated with acute gouty arthritis. The short-term treatment of moderate pain associated with dental surgery. Base the decision to prescribe a selective COX-2 inhibitor on an assessment of the individual patient's overall risks. **DOSAGE AND ADMIN-ISTRATION** Take orally with or without food. Onset of action may be faster when administered without food, and should be considered when rapid relief is needed. **Osteoarthritis:** 30 mg once daily. In some patients with insufficient relief from symptoms, an increased dose of 60 mg once daily may increase efficacy. **Rheumatoid arthritis:** 90 mg once daily. **Ankylosing spondylitis:** 90mg once daily. For acute pain conditions, etoricoxib should be used only for the acute symptomatic period. **Acute gouty arthritis:** 120 mg once daily limited to a maximum of 8 days. **Postoperative dental surgery pain:** 90 mg once daily, limited to a maximum of 3 days. Some patients may require additional postoperative analgesia. Each dose above is the maximum recommended dose for each condition and should not be exceeded. As the cardiovascular risks of etoricoxib may increase with dose and duration of exposure, use for the shortest duration possible and use the lowest effective daily dose. Re-evaluate periodically the patient's need for symptomatic relief and response to therapy, especially in osteoarthritis patients. **Hepatic insufficiency:** mild (Child-Pugh score 5-6): regardless of indication, do not ex-ceed a dose of 60 mg daily, moderate (Child-Pugh score 7-9): regardless of indication, do not exceed 30 mg once daily. **Renal insuffi-ciency:** No dosage adjustment necessary for patients with creatinine clearance  $\geq 30$  ml/min. **CONTRAINDICATIONS** History of hy-persensitivity to any component of this product. Active peptic ulceration or gastro-intestinal (GI) bleeding. Patients who have experienced bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema or urticaria or allergic type reactions after aspirin or NSAIDs including COX-2 inhibitors. Pregnancy and lactation. Severe hepatic dysfunction (serum albumin  $<25$  g/l or Child-Pugh score  $\geq 10$ ). Estimated creatinine clearance  $<30$  ml/min. Children and adolescents under 16 years of age. Inflammatory bowel disease. Con-gestive heart failure (NYHA II-IV). Patients with hypertension whose blood pressure is persistently elevated above 140/90mmHg and has not been adequately controlled. Established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular dis-ease. **PRECAUTIONS AND WARNINGS** **Gastro-intestinal effects** Upper GI complications (perforations, ulcers or bleedings), some with fatal outcome have occurred in patients taking etoricoxib. Caution is advised in patients most at risk of developing a GI complica-tion with NSAIDs: elderly, those on any other NSAID or aspirin concomitantly, or those with a prior history of GI disease. There is a further increase in the risk of GI adverse effects (GI ulceration or other GI complications) when etoricoxib is taken together with as-pirin (even at low doses). A significant difference in GI safety between selective COX-2 inhibitors + acetylsalicylic acid vs NSAIDs + acetylsalicylic acid has not been demonstrated in long-term clinical trials. **Cardiovascular** Clinical trials suggest that the selective COX-2 inhibitor class of drugs may be associated with a risk of thrombotic events (especially MI and stroke), relative to placebo and some NSAIDs. As the cardiovascular risks of etoricoxib may increase with dose and duration of exposure, use for the shortest dura-tion possible and use the lowest effective daily dose. Re-evaluate periodically the patient's need for symptomatic relief and response to therapy, especially in those with osteoarthritis. Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with etoricoxib after careful consideration. COX-2 selective in-hibitors are not a substitute for acetylsalicylic acid for prophylaxis of cardiovascular thromboembolic diseases because of their lack of antiplatelet effect. Therefore antiplatelet therapies should not be discontinued. **Renal effects** Consider monitoring renal function in patients with pre-existing significantly impaired renal function, uncompensated heart failure, or cirrhosis. **Fluid retention, oedema and hypertension** Exercise caution in patients with a history of cardiac failure, left ventricular dysfunction, or hypertension and pre-exist-ing oedema from any other reason, as fluid retention, oedema and hypertension have been observed in patients taking etoricoxib. All Nonsteroidal Antiinflammatory Drugs (NSAIDs), including etoricoxib, can be associated with new onset or recurrent congestive heart failure. Take appropriate measures, including discontinuation of etoricoxib where there is clinical evidence of deterioration in the condition of these patients. Etoricoxib may be associated with more frequent and severe hypertension than some other NSAIDs and selective COX-2 inhibitors, particularly at high doses. Therefore, hypertension should be controlled before treatment with etoricoxib (see section 4.3) and special attention should be paid to blood pressure monitoring during treatment with etoricoxib. Blood pressure should be monitored within two weeks after initiation of treatment and periodically thereafter. If blood pressure rises significantly, consider alternative treatment. **Hepatic effects** Elevations of ALT and/or AST ( $>3$  times the upper limit of normal) have been reported in approximately 1% of patients treated in trials with etoricoxib 30mg, 60 mg and 90 mg for up to one year. Monitor any patient with symptoms/signs of liver dysfunction or in whom an abnormal liver function test has occurred. Discontinue etoricoxib if signs of hepatic insufficiency occur, or if persistently abnormal liver function tests (3 times the upper limit of normal) are detected. **General** Take appropriate measures and consider discontinuation, if during treatment, patients deteriorate in any of the organ system functions described above. Maintain appropriate medical supervision when treating the elderly and patients with renal, hepatic or cardiac dysfunction with etoricoxib. Use caution when initiating treatment in patients with considerable dehydration. Rehydrate patients prior to starting therapy with etoricoxib. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported very rarely, associated with the use of NSAIDs and some selective COX-2 inhibitors. Discontinue at the first signs of skin rash, mucosal lesions or any other signs of hypersensitivity as hypersensitivity reactions (anaphylaxis, angioedema) have been reported. Etoricoxib may mask fever. Arcoxia® tablets contain lactose: do not use in patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **INTER-ACTIONS** **Interactions (pharmacodynamic):** Oral anticoagulants: Exercise caution when coadministering with warfarin and other oral anticoagulants. Closely monitor the prothrombin time INR when therapy with etoricoxib is initiated or the dose changed in patients receiving oral anticoagulants or similar agents, particularly in the first few days. **Diuretics, ACE-inhibitors and Angiotensin II Antago-nists:** NSAIDs may reduce the effect of diuretics and antihypertensive drugs. In some patients with compromised renal function, the co-administration of an ACE inhibitor or AIIA and cyclo-oxygenase inhibitors may result in further deterioration of renal function in-cluding possible acute renal failure, which is usually reversible. Administer cautiously, especially in the elderly. Patients should be adequately hydrated. Consider monitoring renal function at initiation of therapy and periodically thereafter. **Aspirin:** etoricoxib can be used concomitantly with aspirin at doses used for cardiovascular prophylaxis (low dose aspirin). However, concomitant adminis-tration of low dose aspirin with etoricoxib may result in an increased rate of GI ulceration or other complications compared to use of etoricoxib alone. Concomitant administration of etoricoxib with doses of aspirin above those for cardiovascular prophylaxis, or with other NSAIDs is not recommended. **Ciclosporin/tacrolimus:** monitor renal function when etoricoxib and either ciclosporin or tacrolimus is used in combination. **Interactions (pharmacokinetic):** The effect of etoricoxib on the pharmacokinetics of other drugs: Lithium: the plasma concentration of lithium is increased by NSAIDs, therefore monitor and adjust blood lithium and lithium dosage if necessary. **Methotrexate:** adequate monitoring is recommended for methotrexate-related toxicity when etoricoxib and methotrexate are

administered concomitantly. **Oral Contraceptives (OC):** Administration of etoricoxib 60 mg with an OC containing 35 mcg ethinyl estro-diol (EE) and 0.5 to 1 mg norethindrone for 21 days increased the steady state  $AUC_{0-24h}$  of EE by 37%. Administration of etoricoxib 120 mg with the same OC, concomitantly or separated by 12 hours, increased the steady state  $AUC_{0-24h}$  of EE by 50 to 60%. Consider this increase in EE concentration when selecting an oral contraceptive for use with etoricoxib. An increase in EE exposure can increase the incidence of adverse events associated with oral contraceptives. **Hormone Replacement Therapy:** 120 mg etoricoxib administered with 0.625 mg Premarin™ (Wyeth) for 28 days increased the mean steady state  $AUC_{0-24h}$  of unconjugated estrone (41%), equilin (76%) and 17- $\beta$ -estradiol (22%). Although the clinical significance is unknown, take into consideration the increase in estrogenic concentra-tion when selecting HRT as the increase in estrogen exposure might increase the risk of adverse events associated with HRT. **Di-goxin:** Patients at high risk of digoxin toxicity should be monitored for an increase in digoxin  $C_{max}$  when etoricoxib and digoxin are administered concomitantly. **Effect of etoricoxib on drugs metabolised by sulfo-transferases:** Etoricoxib is an inhibitor of human sulfo-transferase activity, particularly SULT1E1 and has been shown to increase the serum concentrations of ethinyl estradiol. It may be prudent to exercise care when administering etoricoxib concurrently with other drugs primarily metabolised by human sulfo-transferases (e.g. oral salbutamol and minoxidil). **Effect of etoricoxib on drugs metabolised by CYP isoenzymes:** Based on *in vitro* studies, etoricoxib is not expected to inhibit cytochromes P450 (CYP) 1A2, 2C9, 2C19, 2D6, 2E1 or 3A4. In a study in healthy subjects, daily ad-ministration of etoricoxib 120 mg did not alter hepatic CYP3A4 activity as assessed by the erythromycin breath test. **Effects of other drugs on the pharmacokinetics of etoricoxib:** The main pathway of etoricoxib metabolism is dependent on CYP enzymes. CYP3A4 appears to contribute to the metabolism of etoricoxib *in vivo*. **Ketoconazole:** a potent inhibitor of CYP3A4, dosed at 400 mg once a day for 11 days to healthy volunteers did not have any clinically important effect on the single-dose pharmacokinetics of 60 mg etoricoxib (43% increase in  $AUC$ ). **Voriconazole and Miconazole:** Co-administration of either oral voriconazole or topical miconazole oral gel, strong CYP3A4 inhibitors, with etoricoxib caused a slight increase in exposure to etoricoxib, but is not considered to be clinically meaningful based on published data. **Rifampicin:** Co-administration of etoricoxib with rifampicin, a potent inducer of CYP enzymes, produced a 65% decrease in etoricoxib plasma concentrations, an interaction which may result in recurrence of symptoms. **Antacids:** Antacids do not affect the pharmacokinetics of etoricoxib to a clinically relevant extent. **PREGNANCY AND LACTATION** **Pregnancy:** contra-indicated in the first, second and third trimesters of pregnancy. **Lactation:** contra-indicated. **Fertility:** Use of etoricoxib is not recommended in women attempting to conceive. **SIDE EFFECTS** The following undesirable effects were reported at an incidence greater than placebo in clinical trials in patients with OA, RA, AS or chronic low back pain treated with etoricoxib 30mg, 60mg or 90mg up to the recommended dose for up to 12 weeks, in MEDAL Program studies for up to 3 years, in short term acute pain studies for up to 7 days or in post-marketing experience: [Very common ( $\geq 1/10$ ) Common ( $\geq 1/100$  to  $<1/100$ ) Uncommon ( $\geq 1/1000$  to  $<1/100$ ) Rare ( $\geq 1/10,000$  to  $<1/10,000$ ) Very rare ( $<1/10,000$ ) not known (cannot be estimated from the available data)] **Infections and infestations:** Common: alveolar osteitis Uncommon: gastro-enteritis, upper respiratory infection, urinary tract infection. **Blood and lymphatic sys-tem disorders:** Uncommon: anaemia (primarily associated with gastrointestinal bleeding), leukopenia, thrombocytopenia. **Immune system disorder:** Uncommon: hypersensitivity \*\* Rare: angioedema, anaphylactic/anaphylactoid reactions including shock. **Metabo-lism and nutrition disorders:** Common: oedema/fluid retention Uncommon: appetite increase or decrease, weight gain. **Psychiatric disorders:** Uncommon: anxiety, depression, mental acuity decreased, hallucinations. Rare: confusion, restlessness. **Nervous system disorder:** Common: dizziness, headache. Uncommon: dysgeusia, insomnia, paraesthesia/hypaesthesia, somnolence. **Eye disorders:** Uncommon: blurred vision, conjunctivitis. **Ear and labyrinth disorders:** Uncommon: tinnitus, vertigo. **Cardiac disorders:** Common: pal-pitations, arrhythmia Uncommon: atrial fibrillation, tachycardia, congestive heart failure, non-specific ECG changes, angina pectoris, myocardial infarction\*. **Vascular disorders:** Common: hypertension. Uncommon: flushing, cerebrovascular accident\*, transient is-chaemic attack, hypertensive crisis, vasculitis. **Respiratory, thoracic and mediastinal disorders:** Common: bronchospasm Uncom-mon: cough, dyspnoea, epistaxis. **Gastro-intestinal disorders:** Very common: abdominal pain Common: constipation, flatulence, gas-tritis, heartburn/acid reflux, diarrhoea, dyspepsia/epigastric discomfort, nausea, vomiting, oesophagitis, oral ulcer Uncommon: abdominal distention, bowel movement pattern change, dry mouth, gastroduodenal ulcer, peptic ulcers including gastrointestinal perforation and bleeding, irritable bowel syndrome, pancreatitis. **Hepatobiliary disorders:** Common: ALT increased, AST increased. Rare: hepatitis, hepatic failure, jaundice. **Skin and subcutaneous tissue disorders:** Common: ecchymosis Uncommon: facial oedema, pruritus, rash, erythema, urticaria. Rare: Stevens-Johnson syndrome, toxic epidermal necrolysis, fixed drug eruption. **Musculoskel-et al and connective tissue disorders:** Uncommon: muscular cramp/spasm, musculoskeletal pain/stiffness. **Renal and urinary disor-ders:** Uncommon: proteinuria, serum creatinine increased, renal failure/renal insufficiency. **General disorders and administration site conditions:** Common: asthenia/fatigue, flu-like disease. Uncommon: chest pain. **Investigations:** Uncommon: blood urea nitrogen in-creased, creatine phosphokinase increased, hyperkalaemia, uric acid increased. Rare: blood sodium decreased. The following seri-ous undesirable effects have been reported in association with the use of NSAIDs and cannot be ruled out for etoricoxib: nephrotic-ity including interstitial nephritis and nephrotic syndrome. \* Based on analyses of long-term placebo and active controlled clinical trials, selective COX-2 inhibitors have been associated with an increased risk of serious thrombotic arterial events, including myocar-dial infarction and stroke. The absolute risk for such events is unlikely to exceed 1% per year based on existing data (uncommon). \*\* Hypersensitivity includes the terms "allergy", "drug allergy", "drug hypersensitivity", "hypersensitivity", "hypersensitivity NOS", "hypersensitivity reaction" and "non-specific allergy". **PACKAGE QUANTITIES** 30 mg and 60 mg Tablets: packs of 28 tablets. 90 mg Tablets: packs of 5 and 28 tablets. 120 mg Tablets: packs of 7 and 28 tablets. **Legal Category:** POM. **Marketing Authorisation num-bers:** Tablets: 30 mg PA 1286/7/1, Tablet 60 mg PA 1286/7/2, Tablet 90 mg PA 1286/7/3, Tablet 120 mg PA 1286/7/4. **Marketing Authorisation holder:** Merck Sharp & Dohme Ireland (Human Health) Limited, Red Oak North, South County Business Park, Leopardstown, Dublin 18. **Date of revision:** April 2013. © Merck Sharp & Dohme Ireland (Human Health) Limited 2013. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). **Date of preparation:** May 2013

**References:** 1. Arcoxia SPC. a. Doses greater than those recommended for each indication have either not demonstrated additional efficacy or have not been studied. Due to cardiovascular risks, the shortest duration possible and the lowest effective daily dose of ARCOXIA® should be used. b. The recommended dose for osteoarthritis is 30 mg once daily. An increased dose of 60 mg once daily may increase efficacy. The dose for osteoarthritis should not exceed 60 mg daily.



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



# Help Protect Your Post-Menopausal Patients From Osteoporotic Fractures

With 5600 IU of Vitamin D



The Only Osteoporosis Therapy With 5600 IU of Vitamin D That Provides Demonstrated Fracture Prevention at the Hip and Spine,<sup>1,2</sup> in one tablet



Actual size

Updated NOF<sup>3</sup> guidelines recommend 800–1000 IU of vitamin D per day for adults ≥50 years<sup>3</sup>

**FOSAVANCE** 70 mg/2800 IU Tablets (70 mg alendronate acid as alendronate sodium trihydrate and 70 micrograms (2800 IU) colecalciferol (vitamin D<sub>3</sub>)). **FOSAVANCE** 70 mg/5600 IU Tablets (70 mg alendronate acid as alendronate sodium trihydrate and 140 micrograms (5600 IU) colecalciferol (vitamin D<sub>3</sub>)). **ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing.

**PRESENTATION** **FOSAVANCE** 70 mg/2800 IU Tablets Capsule-shaped, white to off-white tablets marked with an outline of a bone image on one side, and '710' on the other, containing 70 mg alendronate acid as alendronate sodium trihydrate and 70 micrograms (2800 IU) colecalciferol (vitamin D<sub>3</sub>). **FOSAVANCE** 70 mg/5600 IU Tablets Modified rectangle-shaped, white to off-white tablets, marked with an outline of a bone image on one side, and '270' on the other, containing 70 mg alendronate acid as alendronate sodium trihydrate and 140 micrograms (5600 IU) colecalciferol (vitamin D<sub>3</sub>).

**USES** Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency and for 'Fosavance' 5600 for patients not receiving Vitamin D supplementation. 'Fosavance' reduces the risk of vertebral and hip fractures. **DOSAGE AND ADMINISTRATION** The recommended dose is one tablet **once weekly**. Patients should be instructed that if they miss a dose of FOSAVANCE they should take one tablet on the morning after they remember. They should not take two tablets on the same day but should return to taking one tablet once a week, as originally scheduled on their chosen day. Due to the nature of the disease process in osteoporosis, 'Fosavance' is intended for long-term use. The optimal duration of bisphosphonate treatment for osteoporosis has not been established. The need for continued treatment should be re-evaluated periodically based on the benefits and potential risks of FOSAVANCE on an individual patient basis, particularly after 5 or more years of use. Patients must be advised to follow the instructions below: *For adequate absorption of alendronate:* 'Fosavance' must be taken with water only (not mineral water) at least 30 minutes before the first food, beverage, or medicinal product (including antacids, calcium supplements and vitamins) of the day. Other beverages (including mineral water), food and some medicinal products are likely to reduce the absorption of alendronate. *The following instructions should be followed exactly in order to minimise the risk of oesophageal irritation and related reactions:* • Swallow 'Fosavance' only upon arising for the day with a full glass of water (not less than 200 ml or 7 fl.oz.). • Patients should only swallow FOSAVANCE whole. Patients should not crush or chew the tablet or allow the tablet to dissolve in their mouths because of a potential for oropharyngeal ulceration. • Do not lie down until after the first food of the day. • Do not lie down for at least 30 minutes after taking 'Fosavance'. • Do not take at bedtime or before rising for the day. Patients should receive supplemental calcium if intake from diet is inadequate. Additional supplementation with vitamin D should be considered on an individual basis taking into account vitamin D intake from vitamins and dietary supplements. Equivalence of 2800 IU of vitamin D, weekly in 'Fosavance' to daily dosing of vitamin D 400 IU has not been studied. Equivalence of intake of 5600 IU of vitamin D, weekly in FOSAVANCE to daily dosing of vitamin D 800 IU has not been studied. *Use in the elderly:* No dosage adjustment is necessary. Use in renal impairment: No dose adjustment is necessary for patients where GFR is greater than 35 ml/min. Alendronate is not recommended for patients with renal impairment where GFR is <35 ml/min. *Use in children and adolescents:* Not recommended. **CONTRAINDICATIONS** Oesophageal abnormalities and other factors which delay oesophageal emptying, such as stricture or achalasia. Inability to stand or sit upright for at least 30 minutes. Hypersensitivity to alendronate or to any of the excipients. **HYPOCALCAEMIA** Alendronate can cause local irritation of the upper gastro-intestinal mucosa and potentially worsen any underlying disease. Because there is a potential for worsening of the underlying disease, caution should be used when alendronate is given to patients with active upper gastro-intestinal problems, such as dysphagia, oesophageal disease, gastritis, duodenitis, or ulcers, or with a recent history (within the previous year) of gastro-intestinal disease such as peptic ulcer, or active gastro-intestinal bleeding, or surgery of the upper gastro-intestinal tract other than pyloroplasty. In patients with known Barrett's oesophagus, prescribers should consider the benefits and potential risks of alendronate on an individual patient basis. Oesophageal reactions (sometimes severe and requiring hospitalisation), such as oesophagitis, oesophageal ulcers and oesophageal erosions, rarely followed by oesophageal strictures, have been reported in patients receiving alendronate. Physicians should be alert to any signs or symptoms of a possible oesophageal reaction, and patients should be instructed to discontinue alendronate and seek medical attention if they develop symptoms of oesophageal irritation such as dysphagia, pain on swallowing, retrosternal pain, or now or worsening heartburn. The risk of severe oesophageal adverse reactions appear to be greater in patients who fail to take alendronate properly and/or continue to take alendronate after developing symptoms suggestive of oesophageal irritation. It is very important that the full dosing instructions are provided to, and understood by the patient. Patients should be informed that failure to follow these instructions may increase their risk of oesophageal problems. While no increased risk was observed in extensive clinical trials with alendronate, there have been rare (post-marketing) reports of gastric and duodenal ulcers, some severe and with complications. Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection (including osteomyelitis) has been reported in patients with cancer receiving treatment regimens including primarily intravenously administered bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates. The following risk factors should be considered when evaluating an individual's risk of developing osteonecrosis of the jaw: potency of the bisphosphonate (highest for zoledronic acid), route of administration (see above) and cumulative dose, cancer, chemotherapy, radiotherapy, corticosteroids, smoking, a history of dental disease, poor oral hygiene, periodontal disease, invasive dental procedures and poorly fitting dentures. A dental examination with appropriate preventive dentistry should be considered prior to treatment with oral bisphosphonates in patients with poor dental status. While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. During bisphosphonate treatment, all patients should be encouraged to maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain, or swelling. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment. Bone, joint and/or muscle pain has been reported in patients taking bisphosphonates. In post-marketing experience, these symptoms have rarely been severe and/or incapacitating. The time to onset of symptoms varied from one day to several months after starting treatment. Most patients had relief of symptoms after stopping treatment. A subset had recurrence of symptoms when rechallenged with the same medicinal product or another bisphosphonate. Atypical subtrochanteric and diaphyseal femoral fractures have been reported with bisphosphonate therapy, primarily in patients receiving long-term treatment for osteoporosis. These transverse or short oblique, fractures can occur anywhere along the femur from just below the lesser trochanter to just above the supracondylar flare. These fractures occur after minimal or no trauma and some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture. Fractures are often bilateral; therefore the contralateral femur should be examined in bisphosphonate-treated patients who have sustained a femoral shaft fracture. Poor healing of these fractures has also been reported. Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur fracture should be considered pending evaluation of the patient, based on an individual benefit/risk assessment. 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. Cause of osteoporosis other than oestrogen deficiency and ageing should be considered. Hypocalcaemia must be corrected before initiating therapy with 'Fosavance'. Other disorders affecting mineral metabolism (such as vitamin D deficiency and hypoparathyroidism) should also be effectively treated before starting 'Fosavance'. The content of vitamin D in 'Fosavance' is not suitable for correction of vitamin D deficiency. In patients with these conditions, serum calcium and symptoms of hypocalcaemia should be monitored during therapy with 'Fosavance'. Due to the positive effects of alendronate in increasing bone mineral, decreases in serum calcium and phosphate may occur especially in patients taking glucocorticoids in whom calcium absorption may be decreased. *Colecalciferol:* Vitamin D<sub>3</sub> may increase the magnitude of hypercalcaemia and/or hypercalcaemia when administered to patients with disease associated with unregulated overproduction of calcitriol (e.g. leukaemia, lymphoma, sarcoidosis). Urine and serum calcium should be monitored in these patients. Patients with malabsorption may not adequately absorb vitamin D<sub>3</sub>. *Excipients:* Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose isomaltase insufficiency should not take 'Fosavance'. *Drug interactions:* If taken at the same time, it is likely that food, beverages (including mineral water), calcium supplements, antacids, and some oral medicinal products will interfere with absorption of alendronate. Therefore, patients must wait at least 30 minutes after taking alendronate before taking any other oral medicinal product. Since NSAID use is associated with gastrointestinal irritation, caution should be used during concomitant use with alendronate. *Colecalciferol:* Olestra, mineral oils, orlistat, and bile acid sequestrants (e.g. cholestyramine, colestipol) may impair the absorption of vitamin D. Anticonvulsants, cimetidine and thiazides may increase the catabolism of vitamin D. Additional vitamin D supplements may be considered on an individual basis. *Use in pregnancy and lactation:* 'Fosavance' is only intended for use in postmenopausal women and therefore it should not be used during pregnancy or in breast-feeding women. There are no adequate data from the use of 'Fosavance' in pregnant women. It is not known whether alendronate is excreted into human breast milk. *Colecalciferol* and some of its active metabolites pass into breast milk. Fertility There are no data on fetal risk in humans. However, there is a theoretical risk of fetal harm, predominantly skeletal, if a woman becomes pregnant after completing a course of bisphosphonate therapy. **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES** Certain adverse reactions that have been reported with FOSAVANCE may affect some patients' ability to drive or operate machinery. Individual responses to FOSAVANCE may vary. **SIDE EFFECTS** Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/10,000), rare (≥ 1/10,000 to < 1/100,000), very rare (< 1/100,000).

<b>Immune system disorders:</b>	Rare: hypersensitivity reactions including urticaria and angioedema
<b>Metabolism and nutrition disorders:</b>	Rare: symptomatic hypocalcaemia, often in association with predisposing conditions
<b>Nervous system disorders:</b>	Common: headache, dizziness <sup>1</sup> Uncommon: dysgeusia <sup>1</sup>
<b>Eye disorders:</b>	Uncommon: eye inflammation (uveitis, scleritis, or episcleritis)
<b>Ear and labyrinth disorders:</b>	Common: vertigo <sup>1</sup>
<b>Gastrointestinal disorders:</b>	Common: abdominal pain, dyspepsia, constipation, diarrhoea, flatulence, oesophageal ulcer, dysphagia, abdominal distension, acid regurgitation Uncommon: nausea, vomiting, gastritis, oesophagitis, oesophageal erosions, melena <sup>1</sup> Rare: oesophageal stricture, oropharyngeal ulceration <sup>1</sup> , upper gastrointestinal PUBs (perforation, ulcers, bleeding)
<b>Skin and subcutaneous tissue disorders:</b>	Common: alopecia <sup>1</sup> , pruritus <sup>1</sup> Uncommon: rash, erythema Rare: rash with photosensitivity, severe skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis <sup>1</sup>
<b>Musculoskeletal and connective tissue disorders:</b>	Very common: musculoskeletal (bone, muscle or joint) pain which is sometimes severe <sup>1</sup> Common: joint swelling <sup>1</sup> Rare: osteonecrosis of the jaw <sup>1</sup> ; stress fractures of the proximal femoral shaft <sup>1</sup> ; atypical subtrochanteric and diaphyseal femoral fractures (bisphosphonate class adverse reaction) <sup>1</sup>
<b>General disorders and administration site conditions:</b>	Common: asthenia <sup>1</sup> , peripheral oedema <sup>1</sup> Uncommon: transient symptoms as in an acute-phase response (myalgia, malaise and rarely, fever), typically in association with initiation of treatment <sup>1</sup>

<sup>1</sup>Frequency in Clinical Trials was similar in the drug and placebo group. <sup>2</sup>This adverse reaction was identified through post-marketing surveillance. The frequency of rare was estimated based on relevant clinical trials. <sup>3</sup>Identified in postmarketing experience.

**OVERDOSE** Alendronate Hypocalcaemia, hypophosphataemia and upper gastrointestinal adverse reactions, such as upset stomach, heartburn, oesophagitis, gastritis, or ulcer, may result from oral overdose. No specific information is available on the treatment of overdose with alendronate. In case of overdose with FOSAVANCE, milk or antacids should be given to bind alendronate. Owing to the risk of oesophageal irritation, vomiting should not be induced and the patient should remain fully upright. *Colecalciferol/Vitamin D* toxicity has not been documented during chronic therapy in generally healthy adults at a dose less than 10,000 IU/day. In a clinical study of healthy adults a 4,000 IU daily dose of vitamin D<sub>3</sub> for up to five months was not associated with hypercalcaemia or hypercalcaemia.

**PACKAGE QUANTITIES** 'Fosavance' 70 mg/2800 IU Tablets 4 tablets. 'Fosavance' 70 mg/5600 IU Tablets 4 tablets. **POM Date of review:** June 2011 Marketing Authorisation numbers: 'Fosavance' 70 mg/2800 IU Tablets EU/1/05/310/002 'Fosavance' 70 mg/5600 IU Tablets EU/1/05/310/007

**Marketing Authorisation Holder:** Merck Sharp & Dohme Limited, Hertford Road, Hoddeston, Herts SG11 9BU, UK. 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, 2012. All rights reserved. Date of preparation: September 2012.

**References:** 1. Data on file, MSD. 2. Schnitzer T, Bone HG, Crepaldi G, et al; Alendronate Once-Weekly Study Group. Therapeutic equivalence of alendronate 70 mg once-weekly and alendronate 10 mg daily in the treatment of osteoporosis. *Aging Clin Exp Res.* 2000;12(1):1–12. 3. NOF Scientific Statement. National Osteoporosis Foundation's Updated Recommendations for Calcium and Vitamin D<sub>3</sub> Intake, 13 March 2007. Available at [www.nof.org/prevention/calcium\\_and\\_vitaminD.htm](http://www.nof.org/prevention/calcium_and_vitaminD.htm). Accessed March 2013. A NOF-National Osteoporosis Foundation



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







# It's time to change your ideas about ORENCIA®

Sustained protection  
from structural damage<sup>1</sup>



ORENCIA®  
(abatacept)

ORENCIA® is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (MTX) or a Tumour Necrosis Factor (TNF) – alpha inhibitor.

**ORENCIA® (abatacept) PRESCRIBING INFORMATION.** See Summary of Product Characteristics before prescribing. **PRESENTATION:** 250mg powder for concentrate for solution for IV infusion containing 250mg abatacept per vial. Each ml contains 25mg of abatacept, after reconstitution. **INDICATION:** Rheumatoid arthritis: Treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a Tumour Necrosis Factor (TNF) – alpha inhibitor. A reduction in the progression of joint damage and improvement of physical function has been demonstrated during combination treatment with abatacept and methotrexate. Polyarticular juvenile idiopathic arthritis (pJIA): treatment of moderate to severe active pJIA in paediatric patients six years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. **DOSAGE:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. *Adult and elderly patients weighing < 60kg:* 500mg (2 vials). *Patients weighing ≥ 60kg ≤ 100kg:* 750mg (3 vials). *Patients weighing > 100kg:* 1000mg (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, Orenzia should be given at 2 and 4 weeks, then every 4 weeks thereafter. Consider therapeutic alternatives if there is no response within 6 months. Use in children below 6 years of age is not recommended. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections. **WARNINGS AND PRECAUTIONS:** *Infections:* Treatment should not be initiated in patients with active infections until infections are controlled. Caution should be exercised when considering the use in patients with a history of recurrent infections, in patients with underlying conditions which may predispose them to infection or in patients on concomitant immunosuppressive therapy. Any patient who develops a new infection should be closely monitored and Orenzia should be discontinued if a patient develops a serious infection. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Monitor for signs of infection when transitioning from a TNF-antagonist to Orenzia. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orenzia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. *Allergic Reactions:* Caution in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions can occur and can be life threatening. Orenzia should be discontinued permanently if a patient develops serious allergic or anaphylactoid reaction. *Malignancies:* The potential role of abatacept in the development of malignancies is unknown, 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 concurrently or within 3 months of discontinuation of Orenzia. It is recommended that patients with pJIA be brought up to date with all immunisations in agreement with current immunisation guidelines, prior to initiating Orenzia therapy. *Blood Glucose Tests:* False elevations on day of infusion can occur, see SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orenzia with a TNF inhibitor is not recommended. No major safety issues were identified with the use of Orenzia 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 up to 14 weeks after last dose. **UNDESIRABLE EFFECTS:** in adult placebo-controlled trials the following adverse drug reactions were reported *Very Common* (≥ 1/10): upper respiratory tract infection; *Common* (≥ 1/100 to < 1/10): Hypertension, flushing, increased blood pressure, headache, paraesthesia, conjunctivitis, abnormal LFTs, dizziness, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, rash, alopecia, pruritus, leukopenia, pain in extremity, fatigue, asthenia, infections including LRTIs, UTIs, herpes infections (including herpes simplex, oral herpes and herpes zoster), rhinitis, pneumonia, influenza *Uncommon* (≥ 1/1,000 to < 1/100): tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, basal cell and squamous cell carcinoma, skin papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, dry eye, reduced visual acuity, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, decreased blood pressure, bronchospasm, wheezing, dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, erythema, hyperhidrosis, arthralgia, amenorrhea, menorrhagia, influenza-like illness, weight increase. *Rare:* Tuberculosis, bacteraemia, gastrointestinal infection, lymphoma, malignant lung neoplasm, throat tightness. In COPD patients, a greater percentage of abatacept than placebo-treated patients developed a serious adverse reactions. In paediatric patients with pJIA, adverse reactions were similar in type and frequency to those seen in adults except: *Common* (≥ 1/100 to < 1/10): upper respiratory tract infection (including sinusitis, nasopharyngitis and rhinitis), otitis (media and externa), haematuria, pyrexia. See SmPC for further details. **LEGAL CATEGORY:** POM **MARKETING AUTHORISATION NUMBER:** EU/1/07/389/001, 1 vial pack. **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 3DH. **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:** September 2013. Job No.: 427IE13PR08462-01

Reference: 1. Westhovens R, et al. Disease remission, radiographic non-progression and normalization of function achieved at year 1 are sustained long-term in a majority of patients: 5-year outcomes with abatacept in biologic-naïve patients. ACR/ARHP Scientific Meeting 2009. 16–21 October, Philadelphia, PA. Poster 1657.





# DAY 1 (19th Sept): SCIENTIFIC ORAL PRESENTATIONS



Dr Eamonn Molloy & Prof Gaye Cunnane, Session chairs



Dr Emese Balogh



Dr Eoghan McCarthy



Dr Wei Gao



Ms Aoife Maher

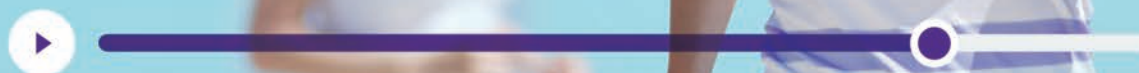


Dr Muhammad Haroon: ISR Young Investigator Award winner for 2013



12 weeks of psoriatic arthritis control for

# Play without pause



After 2 starter doses, 1 dose of Stelara® every 12 weeks can reliably control the signs and symptoms of psoriatic arthritis.<sup>1</sup>



#### STELARA® solution for injection in pre-filled syringe PRESCRIBING INFORMATION

**ACTIVE INGREDIENT(S):** Ustekinumab. Please refer to Summary of Product Characteristics (SmPC) before prescribing. **INDICATION(S):** **Plaque psoriasis:** 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 and PUVA. **Psoriatic arthritis:** Alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **DOSAGE & ADMINISTRATION:** Under the guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis or psoriatic arthritis. Subcutaneous injection. Avoid areas with psoriasis. For self-injecting patients ensure appropriate training, follow-up and monitoring during treatment. **Plaque psoriasis, adults & elderly:** Patients ≤ 100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients >100 kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients). **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. **Children <18 years:** Not recommended. **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, they should be closely monitored and STELARA should not be administered until infection resolves. **Malignancies:** Potential to increase the risk of malignancy. No studies in patients with a 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 immediately. **Immunotherapy:** Not known whether STELARA affects allergy immunotherapy. **Latex sensitivity:** Needle cover contains natural rubber (latex), may cause allergic reactions. **SIDE EFFECTS:** **Common:** dental infections, upper respiratory tract infection, nasopharyngitis,

dizziness, headache, oropharyngeal pain, diarrhoea, nausea, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain, antibodies to ustekinumab. **Other side effects include:** cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema). **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: The safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. **LEGAL CATEGORY:** Prescription Only Medicine. **PRESENTATIONS, PACK SIZES, PRODUCT LICENCE NUMBER:** STELARA 45mg: 1 x 0.5ml pre-filled syringe. EU/1/08/494/003. STELARA 90mg: 1 x 1.0ml pre-filled syringe. EU/1/08/494/004. **MARKETING AUTHORISATION HOLDER:** JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. **FURTHER INFORMATION IS AVAILABLE FROM:** Janssen-Cilag Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK. © Janssen-Cilag Ltd 2013. Prescribing information last revised: 09/2013. PIVER: 0913.

Reporting suspected adverse reactions 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 the online reporting option accessible from the IMB homepage. A downloadable report form is also accessible from the IMB website, which may be completed manually and submitted to the IMB via 'freepost', in addition to the traditional post-paid 'yellow card' option.

FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2. Tel: +353 1 6764971, Fax: +353 1 6762517 Website: [www.imb.ie](http://www.imb.ie), e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

Adverse events should also be reported to Janssen-Cilag Ltd on +44 (0)1494 567447.

Reference: 1. Stelara SMPC Date September 2013 available from [www.medicines.ie](http://www.medicines.ie)

Date of preparation: September 2013. PHIR/STE/0913/0002a







**The Irish Society for  
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**\*Axial Spondyloarthritis**

**Ankylosing spondylitis**

HUMIRA is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

**Axial spondyloarthritis without radiographic evidence of AS**

HUMIRA is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.<sup>1</sup>

**Rheumatoid arthritis**

HUMIRA in combination with methotrexate, is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.<sup>1</sup>

Full prescribing information is available upon request from AbbVie Limited, Block B, Liffey Valley Office Campus, Quarryvale, Co Dublin, Ireland. **Legal category** POM. **Marketing Authorisation Numbers:** EU/1/03/256/001-005, EU/1/03/256/007-010. **Marketing Authorisation Holder:** AbbVie Ltd., Maidenhead, Berkshire SL6 4XE, UK.

**Reference: 1.** For more information on HUMIRA's licensed indications, please refer to Humira's Summary of Product Characteristics available on [www.medicines.ie](http://www.medicines.ie).

IREHUR130278

**Date of Preparation:** September 2013

abbvie





## IRHPS Spring 2014 Update

### Welcome to the Spring Conference 2014.

Firstly I must extend my thanks to the ISR, Michael & Jenny and also to the Pharma companies for their continued support for a wide range of educational opportunities through our bursaries.

We had a successful meeting in Trim in September with presentations on Working with Arthritis by Dr. Katie Robinson, Impact of Fatigue in SLE by Dr Deirdre Connolly and also the Fatigue in Inflammatory Arthritis by Dr. Patricia Minnock.

We again had speakers from within our ranks as the 2 highest scored Abstract Submissions presented their work – many thanks Catherine Cullinane, Physiotherapist, Waterford Regional Hospital who was the inaugural winner of the Professor Barry Bresnihan gold medal award and Martina Fitzpatrick, Physiotherapist, St. Vincent's University Hospital, Dublin who won the IRHPS silver medal. Both are pictured right with representatives from Abbvie who sponsored the awards.

Other awards were the Roche poster awards which were won by Paul Kirwan & Grainne Cussen who have won the opportunity to attend EULAR in Paris in June – pictured right

We also have the People's Choice Poster Award which was jointly won by Trish Fitzgerald & Eileen O'Flynn

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 email [edofficer@irhps.ie](mailto:edofficer@irhps.ie). And keep an eye on our website [www.irhps.ie](http://www.irhps.ie) for news and meetings.

**Rhona Galway**  
IRHPS Chair





# Gain a fresh perspective

INFLECTRA™ is the world's first biosimilar mAb. Designed with equivalent efficacy, safety and quality to reference infliximab<sup>1,2</sup> to increase the treatment options for your rheumatology patients.

Change your perception. Choose INFLECTRA™.

## Abbreviated Indications:

**Rheumatoid arthritis (RA):** in combination with MTX, for reducing the signs and symptoms of RA and to improve physical function in: adult patients with active disease when the response to DMARDs, including MTX, has been inadequate; adult patients with severe, active and progressive disease not previously treated with MTX or other DMARDs.

**Ankylosing spondylitis (AS):** adult patients with severe, active AS who have responded inadequately to conventional treatment.

**Psoriatic arthritis (PsA):** adult patients with active and progressive PsA when the response to previous DMARD therapy has been inadequate: in combination with MTX; or alone in patients who show intolerance to MTX or for whom MTX is contraindicated.



## Abbreviated Prescribing Information – INFLECTRA™ (Infliximab) powder for concentrate for solution for infusion

Please refer to full Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Vial containing 100 mg of infliximab powder for concentrate for solution for infusion. **Indications:** 1) *Rheumatoid arthritis* in adult patients with active disease with inadequate response to disease-modifying antirheumatic drugs (DMARDs) or adult patients with severe, active and progressive disease not previously treated with methotrexate (MTX) or other DMARDs 2) *Adult Crohn's disease* a) In patients with moderately to severely active Crohn's disease 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 contraindications for such therapies. b) In patients with fistulising, active Crohn's disease who have not responded despite conventional treatment (including antibiotics, drainage and immunosuppressive therapy). 3) *Paediatric Crohn's disease* Severe, active Crohn's disease in patients aged 6 to 17 years, who have not responded to conventional therapy including corticosteroid, immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. 4) *Ulcerative colitis* In both adult patients with moderate to severely active ulcerative colitis, and children and adolescents aged 6 to 17 years with severely active ulcerative colitis and an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine; or who are intolerant to or have contraindications for such therapies. 5) *Ankylosing spondylitis* In adult patients with severe active ankylosing spondylitis who have responded inadequately to conventional therapy. 6) *Psoriatic arthritis* In adult patients with active and progressive psoriatic arthritis when response to previous DMARD therapy has been inadequate. 7) *Psoarthritis* In adult patients with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to systemic therapy including cyclosporine, MTX or PUVA. **Dosage & Administration** 1) *Rheumatoid arthritis* 3 mg/kg as an intravenous (IV) infusion repeated 2 and 6 weeks after initiation, then every 8 weeks. Inflectra must be given concomitantly with MTX. 2) *Moderately to severely active Crohn's disease* 5 mg/kg IV infusion repeated 2 weeks after initiation. If a patient does not respond after 2 doses, no additional dose should be given. 3) *Fistulising, active Crohn's disease* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation. If a patient does not respond after 3 doses, no additional dose should be given. 4) *Ulcerative colitis* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation, then every 8 weeks. 5) *Ankylosing spondylitis* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation, then every 6 to 8 weeks. If a patient does not respond by 6 weeks, no additional dose should be given. 6) *Psoriatic arthritis* 5 mg/kg IV infusion repeated at 2 and 6 weeks after initiation, then every 8 weeks. 7) *Psoarthritis* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation, then every 8 weeks. If a patient shows no response after 14 weeks no additional dose should be given. Administer IV over 2 hours initially and monitor for infusion-related reactions.

**Contraindications:** Hypersensitivity to infliximab, to other murine proteins, or to any excipients. Tuberculosis (TB) or other severe infections such as sepsis, abscesses, and opportunistic infections. Moderate or severe heart failure (NYHA class III/IV).

**Warnings and Precautions:** Caution in patients with or at risk of infusion reactions and hypersensitivity. Do not administer in patients with infections, and/or invasive fungal infections. Monitor for TB and do not use in patients with TB. Test for latent/active TB prior to initiation of therapy. Do not use Inflectra in patients with active TB, patients with latent TB must not be initiated on Inflectra therapy until initiation with anti-TB therapy. Monitor closely for infections, including TB before, during and for six months post-treatment. Patients with fistulising Crohn's disease with acute suppurative fistulas must not initiate therapy until source of infection, specifically abscess, is excluded. Test for HBV infection before initiating treatment. Consult expert in treatment for HBV-positive patients. Closely monitor carriers of HBV during and after therapy. In patients with HBV reactivation, stop Inflectra and initiate appropriate therapy. Pregnancy should be avoided during therapy, and for at least 6 months after last infusion. **Adverse effects:** Viral infection, bacterial infection, TB, fungal infection, meningitis, opportunistic infection, parasitic infection, hepatitis B reactivation, lymphoma, non-Hodgkin's lymphoma, Hodgkin's disease, leukaemia, melanoma, hepatosplenic T-cell lymphoma, Merkel cell carcinoma, allergic respiratory symptom, anaphylactic reaction/shock, lupus like syndrome, serum sickness-like reaction, vasculitis, sarcoid-like reaction, depression, insomnia, amnesia, agitation, confusion, somnolence, nervousness, apathy, headache, vertigo, dizziness, hyposensitivity, paraesthesia, seizure, neuropathy, transverse myelitis, demyelinating disorders, conjunctivitis, keratitis, periorbital oedema, hordeolum, endophthalmitis, transient visual loss, tachycardia, palpitation, cardiac failure, arrhythmia, syncope, bradycardia, cyanosis, pericardial effusion, myocardial ischaemia/infarction, hypotension, hypertension, ecchymosis, hot flush, flushing, peripheral ischaemia, thrombophlebitis, haematoma, circulatory failure, petechia, vasospasm, URTI, sinusitis, lower respiratory tract infection, dyspnoea, epistaxis, pulmonary oedema, bronchospasm, pleurisy, pleural effusion, interstitial lung disease, abdominal pain, nausea, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, intestinal perforation/stenosis, diverticulitis, pancreatitis, chelitis, hepatic function abnormal, transaminases increased, hepatitis, hepatocellular damage, cholecystitis, jaundice, liver failure, psoriasis (new onset or worsening), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, bullous eruption, onychomycosis, seborrhoea, rosacea, skin papilloma, hyperkeratosis, abnormal skin pigmentation, Toxic Epidermal Necrolysis, Stevens-Johnson syndrome, erythema multiforme, furunculosis, arthralgia, myalgia, back pain, urinary tract infection, pyelonephritis, vaginitis, infusion related reaction, pain, chest pain, fatigue, fever, injection site reaction, chills, oedema, impaired healing, granulomatous lesion, autoantibody positive, complement factor abnormal. The SmPC should be consulted for further details of adverse effects **Legal**

category: POM Marketing Authorisation Number/Pack: EU/1/13/854/001 (1 vial); EU/1/13/854/002 (2 vials); EU/1/13/854/003 (3 vials); EU/1/13/854/004 (4 vials); EU/1/13/854/005 (5 vials) **Marketing Authorisation Holder:** Hospira UK Limited, Queensway, Royal Leamington Spa, CV31 3RW. Further information is available on request from: Hospira Ireland Ltd, Unit 15, The Park, The Hyde Building, Carrickmines, Dublin 18, Ireland **Date of preparation:** October 2013 (IE/INF/13/0003)

Adverse events should be reported. Reporting forms and information can be found at [www.imb.ie](http://www.imb.ie)  
Adverse events should also be reported to Hospira UK Ltd.  
Telephone Medical Information: +44 (0) 1926 834400

MTX = Methotrexate  
DMARD = Disease-modifying anti-rheumatic drug

## References:

1. INFLECTRA™. European Public Assessment Report (EPAR). Available at: [www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human\\_med\\_001677.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&mid=WC0b01ac058001d124). [Accessed January 2014]. 2. EMA. Guideline on similar biological medicinal products containing monoclonal antibodies – non-clinical and clinical issues. May 2012. Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2012/06/WC500128686.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500128686.pdf) [Accessed January 2014].

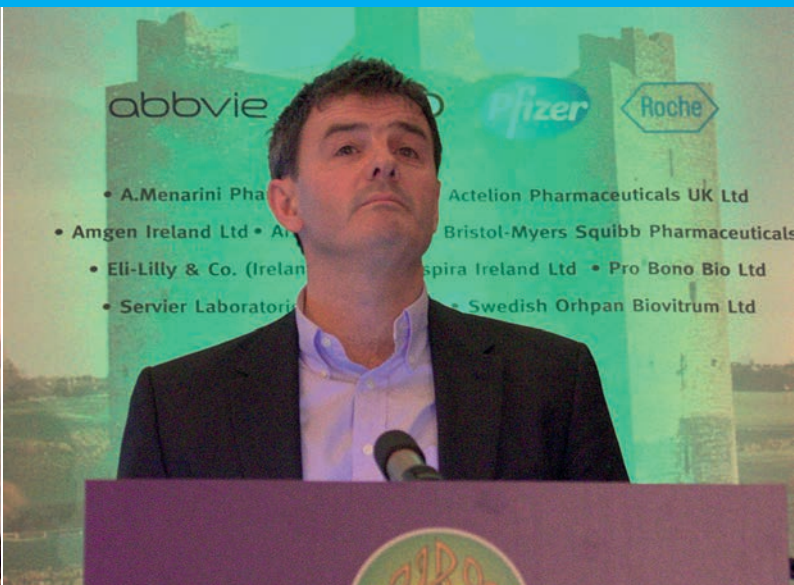
IE/INF/14/0002  
January 2014



# SPEAKERS AT AUTUMN 2013



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Dr Ronan Kavanagh



Prof Jim Lucey



Prof David Isenberg



Prof Philip Conaghan



Prof Robert Inman





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# ISR AUTUMN 2013



Andrea Porter, Lorraine Bermingham, Martyn Smith (Pro Bono Bio)



Dr Grainne Kearns and Dr Suzanne Donnelly



Grainne Kearns and Lorraine O'Neill



Muhammad Haroon and Catriona Buckley



Dr Conor McCarthy, Prof Robert Inman, Dr Barry O'Shea and Dr Ronan Kavanagh



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(febuxostat)

## A daily response<sup>1</sup> For a destructive disease<sup>2</sup>



**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. **Elderly:** 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, and do not re-start febuxostat at any time. **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, febuxostat is not recommended for use in these populations. **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:** Use with caution in patients concomitantly treated with theophylline. Monitor theophylline levels in patients starting febuxostat therapy. **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. **Theophylline:** Inhibition of XO may cause an increase in the theophylline level. Caution advised if these substances are given concomitantly, monitor theophylline levels in patients starting febuxostat therapy. **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/indomethacin/hydrochlorothiazide/warfarin:** Can be co-administered with

colchicine or indomethacin with no dose adjustments necessary. No dose adjustment necessary when administered with hydrochlorothiazide. No dose adjustment necessary for warfarin when administered with febuxostat. **Desipramine/CYP2D6 substrates:** Co administration with other CYP2D6 substrates is not expected to require any dose adjustment for those compounds. **Antacids:** May be taken without regard to antacid use. **Pregnancy and lactation:** Do not use during pregnancy or breast-feeding. Effect on fertility unknown. **Side-Effects: Clinical Studies and post-marketing experience: Common (1-10%):** Gout flares, headache, diarrhoea\*, nausea, liver function test abnormalities\*, rash, oedema. **Uncommon (0.1-1%):** Blood thyroid stimulating hormone increased, diabetes mellitus, hyperlipidemia, decrease appetite, weight increase, decreased libido, insomnia, dizziness, paraesthesia, hemiparesis, somnolence, altered taste, hypoaesthesia, hyposmia, atrial fibrillation, palpitations, ECG abnormal, hypertension, flushing, hot flush, dyspnoea, bronchitis, upper respiratory tract infection, cough, abdominal pain, abdominal distension, gastro-oesophageal reflux disease, vomiting, dry mouth, dyspepsia, constipation, frequent stools, flatulence, gastrointestinal discomfort, cholelithiasis, dermatitis, urticaria, pruritus, skin discolouration, skin lesion, petechiae, rash macular, rash maculopapular, rash papular, arthralgia, arthritis, myalgia, musculoskeletal pain, muscle weakness, muscle spasm, muscle tightness, bursitis, renal failure, nephrolithiasis, haematuria, pollakiuria, proteinuria, erectile dysfunction, fatigue, chest pain, chest discomfort, blood amylase increase, platelet count decrease, WBC decrease, lymphocyte count decrease, blood creatine increase, blood creatinine increase, haemoglobin decrease, blood urea increase, blood triglycerides increase, blood cholesterol increase, 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\*\*, Stevens-Johnson Syndrome\*\*, 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. \*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. **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 or may be found in the SmPC. **Last updated:** January 2013. **References:** 1. Adenuric SmPC. December 2012. 2. McQueen, F.M., et al. *Nat Rev Rheumatol*, 2012. 8(3): p. 173-81.

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Date of item: January 2013  
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Healthcare for Life



## ISR AUTUMN 2013



Prof. Robert Inman and Dr. Ronan Kavanagh



Gráinne O'Leary, Orla Kenny and John Church (Arthritis Ireland)



Dr Muahmmad Haroon and Dr Aamir Saeed



Dr. John Carey, Ann McDermot, Niall Keely



Alice Casey, Cian Deegan, Gill Casey and Dr Eoin Casey: The ISR Life Time Achievement Award was presented to Dr Eoin Casey in 2013



# ISR AUTUMN 2013



Dr Orla Killen



Ms Orla Kenny (Arthritis Ireland)



Prof Gaye Cunnane and Michele Doran



Karina Kelly, Dr Suzanne Donnelly, Dr Sinéad Harney and Kevin McDonagh (Actelion)





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

THINK  
ROACTEMRA<sup>1</sup>

 **RoACTEMRA**<sup>®</sup>  
tocilizumab

RoACTEMRA, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, RoACTEMRA can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoACTEMRA 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 methotrexate.<sup>2</sup>

**ABRIDGED PRESCRIBING INFORMATION. (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]. RoACTEMRA<sup>®</sup> (tocilizumab) 20mg/ml Concentrate for Solution for Infusion**

**Indications:** (i) In combination with methotrexate (MTX), for the treatment of adult patients with moderate to severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists. In these patients, RoACTEMRA can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoACTEMRA 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 methotrexate. (ii) As monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX, for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients ≥ 2 years of age, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. (iii) In combination with MTX, for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients ≥ 2 years of age, who have responded inadequately to previous therapy with MTX. In these patients RoACTEMRA can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. **Dosage and Administration:** Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. RA Patients: Recommended posology is 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by iv infusion over 1 hour. For patients weighing > 100kg, doses > 800mg per infusion are not recommended. No data on doses above 1.2g. Dose adjustments: Dose modification, interruption or in some cases discontinuation of RoACTEMRA recommended in the event of raised liver enzymes, low absolute neutrophil count (ANC) or low platelet count (see SmPC for details). In patients not previously treated with RoACTEMRA, initiation not recommended in patients with an ANC below  $2 \times 10^9/L$ . Closely monitor renal function in patients with moderate to severe renal impairment as RoACTEMRA has not been studied in these patients. No data in patients with hepatic impairment. sJIA Patients: No data in patients < 2 years of age. Posology: In patients > 2 years of age - 8mg/kg diluted to a final volume of 100ml for patients ≥ 30kg or 10 mg/kg diluted to a final volume of 50ml for patients < 30kg once every 2 weeks by iv infusion over 1 hour. Check patient's weight at each visit - refer to SmPC. In the event of raised liver enzymes, low ANC or low platelet count, interrupt/discontinue RoACTEMRA dose or modify/stop concomitant MTX and other medications where appropriate - see SmPC for details. Reduction of RoACTEMRA dose due to laboratory abnormalities not studied in sJIA patients. Clinical improvement is generally seen within 6 weeks of starting RoACTEMRA; reconsider continued therapy if no improvement is seen in this timeframe. pJIA Patients: No data in patients < 2 years of age. Posology: In patients > 2 years of age - 8mg/kg diluted to a final volume of 100ml for patients ≥ 30kg or 10 mg/kg diluted to a final volume of 50ml for patients < 30kg once every 2 weeks by iv infusion over 1 hour. Check patient's weight at each visit - refer to SmPC. In the event of raised liver enzymes, low ANC or low platelet count, interrupt/discontinue RoACTEMRA dose or modify/stop concomitant MTX and other medications where appropriate - see SmPC for details. Reduction of RoACTEMRA dose due to laboratory abnormalities not studied in pJIA patients. Clinical improvement is generally seen within 12 weeks of starting RoACTEMRA; reconsider continued therapy if no improvement is seen in this timeframe. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Warnings and Precautions:** Serious (sometimes fatal) infections reported in patients receiving immunosuppressive agents including RoACTEMRA. Do not initiate in patients with active infection. If serious infection develops interrupt therapy until infection controlled. Caution in patients with history of recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which may predispose patients to infection. Vigilance for the timely detection of serious infection recommended. Advise all patients and parents/guardians of sJIA and pJIA patients to contact their healthcare professional immediately when symptoms suggestive of an infection appear. Screen for latent TB prior to starting therapy. Treat latent TB with standard antimycobacterial therapy before initiating RoACTEMRA. Risk of false negative tuberculin skin and interferon-gamma TB blood test results, especially in severely immunocompromised patients. Advise patients to seek medical attention if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever) suggestive of TB infection occur during or after treatment with RoACTEMRA. Viral reactivation (e.g. hepatitis B) reported with biologic therapies for RA. Patients screening positive for hepatitis excluded from clinical trials. Events of diverticular perforations as complications of diverticulitis reported uncommonly with RoACTEMRA in RA patients. Exercise caution in patients with a history of intestinal ulceration or diverticulitis. Evaluate patients with symptoms of complicated diverticulitis promptly. Serious hypersensitivity reactions reported - may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous infusions 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 with RoACTEMRA. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, stop administration of RoACTEMRA immediately and discontinue therapy permanently. Use with caution in patients with active hepatic disease or hepatic impairment. Not recommended in patients with baseline ALT or AST > 5 x ULN; use with caution in patients with ALT or AST > 1.5 x ULN. Monitor ALT and AST levels for RA, sJIA and pJIA patients according to SmPC - other liver function tests including bilirubin should be considered where indicated. If raised, follow dosage recommendations in SmPC for RA, sJIA and pJIA patients. Risk of neutropenia may be increased in patients previously treated with a TNF antagonist. Continued therapy not recommended in patients who develop an ANC <  $0.5 \times 10^9/L$  or platelet count <  $50 \times 10^9/L$ . In patients not previously treated with RoACTEMRA, initiation not recommended 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. If reduced, follow dosage recommendations in SmPC for RA, sJIA and pJIA patients. Elevations in lipid parameters seen - refer to SmPC. Assess lipid parameters according to SmPC if elevated; manage patients according to local guidelines for hyperlipidaemia. Potential for central demyelination with RoACTEMRA currently unknown; physicians should be vigilant for symptoms of new onset disease. Immunomodulatory medicines may increase malignancy risk in RA patients. Do not give live and live attenuated vaccines concurrently with RoACTEMRA as safety not established - refer to SmPC for further details on immunisations. RA patients should have CV risk factors managed as part of usual standard of care. Not recommended for use with other biological agents. Macrophage activation syndrome (MAS) is a serious life-threatening disorder that may develop in sJIA patients - RoACTEMRA has not been studied in patients during an active MAS episode. Advise patients experiencing dizziness not to drive or use machines until dizziness resolved. Product contains 26.55mg sodium per 1200mg. **Drug Interactions:** Interaction studies only performed in adults. In RA patients, levels of simvastatin (CYP3A4) were decreased by 57% one week following a single dose of tocilizumab to levels similar to or slightly higher than those observed in healthy subjects. Monitor patients taking medicines which are individually adjusted and metabolised by CYP450 3A4, 1A2 or 2C9 when starting or stopping RoACTEMRA, as doses may need to be increased to maintain therapeutic effect. The effect of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy. Refer to SmPC for further details on the effects of RoACTEMRA on cytochrome CYP450 and drug interactions generally. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use effective contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed an 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). **Side Effects and Adverse Reactions:** RA: Most commonly reported ADRs (occurring in ≥ 5% patients treated with tocilizumab monotherapy or with DMARDs) were upper respiratory tract infections, nasopharyngitis, headache, hypertension and increased ALTs. ADRs occurring in patients with RA receiving tocilizumab as monotherapy or in combination with MTX or other DMARDs in the clinical trial double-blind controlled periods. Very Common (≥ 1/10): upper respiratory tract infections and hypercholesterolaemia. Common (≥ 1/100 - < 1/10): cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. sJIA: In general, the ADRs were similar to those seen in RA patients. Infections - Serious infections of varicella and otitis media reported, in addition to infections for RA. Infection reactions - Serious events occurring within 24 hours of infusion in 16% of patients included, but were not limited to rash, urticaria (considered serious), diarrhoea, epigastric discomfort, arthralgia and headache. IgG - decreased levels during therapy. Other - decreases in neutrophil and platelet counts, hepatic transaminase elevations, lipid parameter increases and anti-tocilizumab antibodies observed. Serious or Potentially Serious: serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), gastrointestinal perforations (as complications of diverticulitis), serious hypersensitivity reactions. pJIA: In general, the ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count were more frequently reported in the pJIA population and increased cholesterol was less frequently reported in pJIA than RA. Infections - The incidence of infections leading to dose interruptions was numerically higher in patients weighing < 30 kg, the rate of serious infections was also higher in these patients. Infusion reactions - 20.2% experienced an event within 24 hours of infusion. No clinically significant hypersensitivity reactions associated with tocilizumab and requiring treatment discontinuation were reported. Refer to SmPC for a complete listing of adverse events for RA, sJIA and pJIA. See SmPC section 4.8 for instructions on the reporting of Suspected Adverse Reactions. **Legal Category:** Product subject to medical prescription which may not be renewed (A). **Presentations and 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). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. RoACTEMRA is a registered trademark. 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:** November 2013. Copyright © 2013 by Roche Products (Ireland) Ltd. All rights reserved. **References:** 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. 2. SmPC. RoACTEMRA (tocilizumab) Summary of Product Characteristics, 25 September 2013. Date of item: December 2013. p03/12/13.







Over 20 years  
and 3 million  
patient-years  
collective  
clinical  
experience<sup>9,10</sup>

# The ENBREL way

Indicated for RA, PsA, JIA, AS and PsO<sup>#</sup>

## A unique mechanism of action

- Enbrel is the only fully human soluble tumour necrosis factor (TNF) receptor<sup>1,2,3,4,5,6</sup>
- It works differently than MAB's<sup>1</sup>

## No neutralising antibodies<sup>1</sup>

- Enbrel is not associated with the production of neutralising antibodies in humans

## Enbrel has a short half life (<3 days)<sup>1</sup>

- The half-life of anti-TNF agents should be taken into account if a treatment break is required

## Efficacy

- Registry data and Cochrane Review data support efficacy & safety of Enbrel<sup>7,8</sup>

### Enbrel (etanercept) Abbreviated Prescribing Information

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. 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. 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 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. 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 identified as carriers of hepatitis B virus 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 postmarketing 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 antidiabetic 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 breastfeeding 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 life threatening 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, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) has 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 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. Legal Category: POM. 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. S1B: Product subject to a prescription which may be renewed. 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 363 633 or at [EUMEDINFO@pfizer.com](mailto: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\_6\_1. Date of Prescribing Information: December 2012.

#### References:

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# Rheumatoid Arthritis, Psoriatic Arthritis, Juvenile Idiopathic Arthritis, Ankylosing Spondylitis and Psoriasis. For full prescribing information see the Summary of Product Characteristics.

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