

abbvie



NOVARTIS  
PHARMACEUTICALS



Irish Society  
for Rheumatology

Spring Meeting 2016



14 - 15 April 2016  
Rochestown Park Hotel  
Douglas, Cork





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

THINK RoACTEMRA<sup>1</sup>



NOW  
AVAILABLE IN  
SUBCUTANEOUS (SC)

**ABRIDGED PRESCRIBING INFORMATION** (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). **RoActemra®** (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and **RoActemra®** 162mg solution for injection in pre-filled syringe (RoActemra SC). **Indications:** ABRIDGED PRESCRIBING INFORMATION (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). **RoActemra®** (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and **RoActemra®** 162mg solution for injection in pre-filled syringe (RoActemra SC). **Indications:** **RoActemra SC:** In combination with methotrexate (MTX), for 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 disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients  $\geq 2$  years of age, who responded inadequately to previous therapy with NSAIDs and systemic corticosteroids, (iv) juvenile idiopathic polyarthritis (pJIA) (rheumatoid factor positive or negative and extended oligoarthritis) in patients  $\geq 2$  years of age, who responded inadequately to previous therapy with MTX. **RoActemra IV/SC** can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. **RoActemra IV/SC** has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX for the treatment of adult RA patients. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. **RA:** RoActemra IV: 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients  $>100$ kg, doses  $>800$ mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Rotate injection site frequently. **sJIA (RoActemra IV only):** Patients  $<2$  years of age - no data. Patients  $>2$  years, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 12mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients  $<2$  years of age - no data. Patients  $>2$  years of age, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 10mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. Dose adjustments: For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). **Special Populations:** No data available for RoActemra SC in patients  $<18$  years of age. Closely monitor renal function in patients with moderate to severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients  $>65$  years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Patients to seek medical attention if signs/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment even if they have received premedication with steroids and anti-histamines. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. Not recommended in patients with baseline ALT or AST  $> 5 \times$  ULN; caution in patients with ALT or AST  $> 1.5 \times$  ULN (see SmPC). Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC  $< 0.5 \times 10^9/l$  or platelet count  $< 50 \times 10^3/l$ . Do not initiate RoActemra treatment were ANC is below  $2 \times 10^9/l$ . Caution in patients with low platelet count; monitor neutrophils and platelets in RA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). Not recommended for use with other biological agents. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients - RoActemra not studied in patients during an active MAS episode. Trade name should be clearly recorded in patient file to improve traceability of biological medicines. **Drug Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or CYP2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions). **Fertility, Pregnancy & Lactation:** Women should use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-fetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. No lactation data in humans. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Refer to SmPC. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV:** RA: ADRs occurring in RoActemra trials: Very Common ( $> 1/10$ ): upper respiratory tract infections, 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: ADRs were similar to those seen in RA patients. Serious infections of varicella and otitis media reported (in addition to infections for RA). Hypersensitivity reactions requiring treatment discontinuation occurred in  $< 1\%$  of patients. Other events occurring within 24 hours of infusion (16% of patients) included rash, urticaria (considered serious), diarrhoea, epigastric discomfort, arthralgia and headache. Decreased IgG levels during therapy. pJIA: ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. 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. 20.2% experienced an infusion reaction within 24 hours of infusion. **RoActemra SC:** The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. See SmPC section 4.8 for instructions on the reporting of Suspected Adverse Reactions. **Legal Category:** Subject to medical prescription which may not be renewed (A). **Presentations & Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/001); 200mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** March 2015. **Reference:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. Int. J. Clin. Rheumatol. (2012) 7(1): 9-19. **Date of item:** February 2016. IE/RACE/0216/0001



**RoACTEMRA®**  
tocilizumab





## Welcome Message from the ISR President Dr Sandy Fraser



### Dear Colleagues and Friends

I have great pleasure in welcoming you all to The Rochestown Park Hotel Cork for this year's ISR Spring Meeting. This will be the first meeting for me in my new role as President of the ISR so I would be delighted to gather your views during the meeting of the challenges and problems you feel we face as a society and as a speciality in the years to come. If I can at some point manage to wrestle the chain of office from Professor Kane I will wear it with pride while thinking of the proud history of the society and the great names of Irish Rheumatology who have worn it with such distinction before.

I would like to take this opportunity to thank the outgoing David for his highly successful tenure as President. David brought great energy and ability to the role and the members I know are very grateful for all he achieved during the past few years. His boots will be hard to fill but I am delighted that David has agreed to take up the role of programme director for Rheumatology with the HSE and I look forward to working closely with David to secure as bright a future for Rheumatology in Ireland as possible. David has opened membership of the Clinical Advisory Group, charged with developing a Model of Care for Rheumatology, to all interested consultant rheumatologists in Ireland and the first of quarterly CAG meetings will be the morning of this meeting. Adopting a Model of Care is essential for us to work with the HSE to develop Rheumatology in Ireland in a co-ordinated and appropriately resourced fashion for the future.

It is my belief that Rheumatology faces seismic changes in the coming few years not dissimilar in scale to the metamorphosis which occurred with the advent of the Biologic era in the late 1990's. Exponential advances in the field of biologics are providing us with an ever increasing armoury of molecules and targets whilst at the same time the availability of biosimilar products offers new challenges and opportunities.

I would like to pay special thanks to all our colleagues in the pharmaceutical industry who continue to support the ISR generously. Delivering the best treatments to the right patients at the right time remain common goals for clinicians and industry alike and I believe the colossal advances in rheumatology evident over the past 15 years are testament to this symbiosis.

The academic organisers Sinead Harney and John Ryan have put together an exciting agenda with a clinical emphasis on Connective Tissue Disease and Vasculitis with case discussion and interaction. International and National speakers of the highest quality mean we look forward to a thoroughly fascinating day. We are delighted to welcome Dr. Rob. Hendry from the MPS in Edinburgh who has agreed to address the changing claims environment for rheumatology claims in Ireland and the UK.

I would like to express the appreciation of the ISR Board to the society administration including Michael Dineen and Jenny Howard and I would particularly like to wish Jenny a speedy recovery from her recent hip surgery.

I sincerely hope you all have a great time in Cork .

Yours sincerely

**Dr Sandy Fraser,**  
ISR President



Transforming lives<sup>1</sup>

15 years  
of clinical  
trials  
and real world  
experience<sup>1</sup>

1<sup>st</sup> EMA-  
approved  
anti-TNF  
in RA<sup>17</sup>

More than  
350  
trials<sup>18</sup>

More than  
5700  
publications<sup>19</sup>

4 Over  
million  
patient-years  
of collective  
clinical experience<sup>11</sup>

1 Over  
million  
patients  
treated<sup>110</sup>

of partnership and experience<sup>1</sup>  
15  
years



#### ABBREVIATED PRESCRIBING INFORMATION

##### Enbrel<sup>®</sup>

##### etanercept

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

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

**European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **Legal Category:** S1A. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NU, UK. For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **API Reference Number:** EN 8\_0. **Pfizer number:** 2013-0003980. **Date of Prescribing Information:** July 2014.

<sup>†</sup> Across all indications.

**References:** 1. Scott LJ. Drugs. 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. November 2015. 3. Humira Summary of Product Characteristics. November 2015. 4. Remicade Summary of Product Characteristics. September 2015. 5. Cimzia Summary of Product Characteristics. December 2015. 6. Simponi Summary of Product Characteristics. November 2015. 7. Remicade EMA report 8. <http://clinicaltrials.gov>. Accessed 12 Nov 2014. 9. [www.pubmed.org](http://www.pubmed.org). Accessed 12 Nov 2014. 10. Data on File. January 2015. 11. Data on File. March 2014.

Date of preparation: March 2016. PP-ENB-IRL-0004





## PROGRAMME ISR Spring Meeting

### Rochestown Park Hotel Cork, 14th & 15th April 2016

#### Thursday 14th April

2.30-4.30pm      **Postgraduate Training Day**  
Organised by CUH Academic Team  
*Supported Roche Products Ltd.*

#### Friday 15th April

9.30am            **Registration and welcome**

10.00am          Dr Rachel Jones - Cambridge University  
***"Update on ANCA associated vasculitis"***

10.50am          2 cases with discussion of AAV (SpR)

11.30am          **Coffee & Pharma Exhibition**

12.00noon        Prof David Isenberg - University College London  
***"Lupus" – Expert new perspective on an old disease***

12.50pm          2 cases with discussion of Lupus (SpR)

1.30pm           **Lunch & Pharma Exhibition**

2.30pm           Prof Louise Kenny - UCC  
***"Pregnancy and CTD" - what can go wrong? – how to sort it***

3.20pm           2 cases with discussion of management in pregnancy (SpR)

4.00pm           Medical Protection Insurance Workshop

Dr Rob Hendry  
MPS Medical Director, Edinburgh.  
***"The changing claims environment in rheumatology  
in Ireland and the UK"***

Q&A

4.45pm           **Wrap up**



# FIGHT BACK AGAINST RAPIDLY PROGRESSING RA



## ClickJect® Pre-filled Pen now available

ORENCIA® in combination with methotrexate is licensed as a first line biologic after inadequate DMARDs response for patients with moderate to severe active rheumatoid arthritis<sup>1</sup>

- The first licensed biologic that specifically targets T-cell activation<sup>1,2</sup>
- Over 16,000 patient-years experience in clinical trials<sup>3</sup>
- Clinical efficacy demonstrated over 2 years<sup>4,5</sup>
- Favourable safety profile<sup>3</sup>

NEW

ORENCIA® (abatacept)  
ClickJect®  
PRE-FILLED PEN



Bristol-Myers Squibb

### ORENCIA® (abatacept) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing.  
**PRESENTATION:** 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial. Each ml contains 25 mg of abatacept, after reconstitution; 125 mg pre-filled syringe and pre-filled pen, ClickJect for SC injection. Each pre-filled syringe and pen contains 125 mg of abatacept in 1 ml.

**INDICATION: Rheumatoid arthritis (IV infusion and SC pre-filled syringe and pen):** 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 have been demonstrated during combination treatment with abatacept and methotrexate. See SmPC.  
**Polyarticular Juvenile Idiopathic Arthritis (pJIA) (IV infusion only):** ORENCIA 250 mg powder for concentrate for solution for infusion is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor.

**DOSAGE and ADMINISTRATION:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. **ORENCIA 250 mg powder for concentrate for solution for IV infusion Adults and elderly:** Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≥ 60 kg to ≤ 100 kg: 750 mg (3 vials). Patients weighing > 100 kg: 1000 mg (4 vials). **Treatment of pJIA:** Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg. Paediatric patients weighing 75 kg or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, ORENCIA should be given at 2 and 4 weeks, then every 4 weeks thereafter. **Children:** Use in children below 6 years of age is not recommended.

**ORENCIA 125 mg solution for injection (SC pre-filled syringe and pen) Adults and elderly:** ORENCIA SC may be initiated with or without an intravenous (IV) loading dose. ORENCIA SC should be administered weekly at a dose of 125 mg by subcutaneous injection regardless of weight. If a single IV infusion is given to initiate treatment (IV loading dose before SC administration), the first 125 mg abatacept SC should be administered within a day of the IV infusion, followed by the weekly 125 mg abatacept SC injections. Patients transitioning from ORENCIA IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. **Children:** Administration in children below 18 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: Allergic Reactions:

Caution in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions can occur after the first infusion and can be life threatening. ORENCIA IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactoid reaction. **Infections:** Caution should be exercised when considering use in patients with a history of frequent infections, or underlying conditions which may predispose to infection. Treatment with ORENCIA should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and ORENCIA should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to ORENCIA. Co-administration of ORENCIA with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). ORENCIA treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. **Malignancies:** The potential role of ORENCIA in the development of malignancies is unknown, see SmPC. **Elderly:** Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. **Autoimmune processes:** Theoretical risk of deterioration in autoimmune disease. **Immunisation:** Live vaccines should not be given simultaneously or within 3 months of discontinuation of ORENCIA. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of ORENCIA with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of ORENCIA in combination with sulfasalazine, hydroxychloroquin or leflunomide. **PREGNANCY AND LACTATION:** Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In adult placebo-controlled trials the following adverse drug reactions were reported. **Very Common (≥ 1/10):** upper respiratory tract infection including tracheitis, nasopharyngitis. **Common (≥ 1/100 to < 1/10):** Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), rhinitis, pneumonia, influenza, leukopenia, headache, dizziness, paraesthesia, conjunctivitis, hypertension, flushing, blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), alopecia, pruritus, pain in extremity, fatigue, asthenia, local injection site reactions\*, systemic injection reactions\* (e.g. pruritus, throat tightness, dyspnea) (\*ORENCIA SC) **Uncommon (≥ 1/1,000 to < 1/100):** Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, pelvic inflammatory disease, basal cell and squamous cell carcinoma, skin

papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, blood pressure decreased, bronchospasm, wheezing, dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, erythema, hyperhidrosis, arthralgia, amenorrhea, menorrhagia, influenza like illness, weight increased. **Rare (≥ 1/10,000 to < 1/1,000):** Tuberculosis, bacteraemia, gastrointestinal infection, lymphoma, lung neoplasm malignant, throat tightness. See SmPC for further details.

### LEGAL CATEGORY: POM

**MARKETING AUTHORISATION NUMBER:** ORENCIA 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack; ORENCIA 125 mg solution for injection - EU/1/07/389/008, 4 pre-filled syringes with needle guard and EU/1/07/389/11, ClickJect12 pre-filled pens.

### MARKETING AUTHORISATION HOLDER:

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

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

**DATE OF PREPARATION:** April 2015

**Job No:** 427IE15PR03297-01

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Freepost, HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or [medical.information@bms.com](mailto:medical.information@bms.com)

**REFERENCES:** 1. ORENCIA® Summary of product characteristics 2015; 2. Choy E.H. *Clin Exp Rheumatol* 2009;27:510-18; 3. Genovese M.D. et al. Presented at ACR/ARHP 2012: Poster 1691; 4. Schiff M. et al. *Ann Rheum Dis* 2014;73:86-94; 5. Weinblatt M.E. et al. *Arthr Rheum* 2013;65:28-38. **ABBREVIATIONS:** RA, Rheumatoid Arthritis; DMARD, Disease Modifying Anti-Rheumatic Drugs. **DATE OF APPROVAL:** March 2016 427IE1600040-01





## Speakers

### **Prof Louise Kenny** University College Cork



Prof Louise Kenny is an honours medical graduate of Liverpool Medical School, UK (1993) and a Member of the Royal College of Obstetrics and Gynaecologists (2001). She received her PhD in vascular physiology and pharmacology from the University of Nottingham, UK in 2003. Louise undertook post-doctoral training whilst concurrently completing her clinical training as a Lecturer at the Maternal and Fetal Health Research Centre, University of Manchester, UK. She was awarded CCST by the Specialist Training Authority of the Medical Royal Colleges, UK in 2005 and was appointed as a Senior Lecturer and Consultant Obstetrician at St Mary's Hospital, The University of Manchester. Louise moved to University College Cork in 2006 and took up a post as a Senior Lecturer and Consultant Obstetrician and Gynaecologist at the newly opened Cork University Maternity Hospital where she continued to pursue her long standing clinical and research interest in uteroplacental insufficiency, adverse pregnancy outcome and pregnancy loss. In 2007, Louise was appointed as a Health Research Board Ireland Clinician Scientist. In July 2009, Louise was awarded a Principal Investigator Programme grant from Science Foundation Ireland to develop predictive biomarkers of poor pregnancy outcome, pioneering a new approach to biomarker development by focusing on metabolic changes in plasma. Louise was promoted to Professor of Obstetrics at University College Cork in 2009.

Her work has resulted in three patent applications relating to pregnancy biomarkers and more than >100 peer reviewed original papers, reviews and book chapters. She is the Editor of the 19th Edition of 'Obstetrics by Ten Teachers' - the world's leading undergraduate textbook in obstetrics. In addition, Louise is a reviewer for a wide range of international journals including the American Journal of Obstetrics and Gynecology, the British Journal of Obstetrics and Gynaecology, the British Medical Journal, Clinical Chemistry, Reproductive Sciences and Hypertension and research funding bodies such as the Medical Research Council (UK), the Wellcome Trust, Action Research, the British Heart Foundation, Wellbeing, Sparks, the Health Research Board and Science Foundation Ireland.

At CUMH, she is part of the Perinatal Medicine team and has a particular interest in hypertensive disorders of medicine and other maternal complications.

### **Dr Rachel Jones** Addenbrooke's Hospital, Cambridge



Dr Rachel Jones is a Consultant Nephrologist with a specialist interest in vasculitis at Addenbrooke's Hospital, Cambridge. Since 2005 she has undertaken clinical research with David Jayne in Cambridge, focusing on therapeutic trials in primary systemic vasculitis. In 2011 she gained her CCT and undertook a part-time secondment to GlaxoSmithKline, Stevenage from the University of Cambridge, alongside an Honorary Consultant Nephrologist post. At GlaxoSmithKline she worked on early phase clinical trial design. In June 2013 she returned to the NHS in her current role as a Consultant Nephrologist, working in the Department of Renal Medicine at Addenbrooke's Hospital, including a large specialist vasculitis and lupus clinic.

### **Dr Robert A Hendry** Medical Protection Society, Edinburgh



Robert was born and brought up in Glasgow and studied medicine at Dundee University. After graduating in 1981 he undertook a number of hospital appointments before becoming a partner in an urban teaching practice in Dundee in 1986.

He developed an interest in medical law and completed an MPhil in Law and Ethics in Medicine at Glasgow University in 1992. Having done some consultancy work for the Medical Protection Society and having taught part-time at Dundee University, he took up a permanent appointment as a medicolegal adviser with the Medical and Dental Defence Union of Scotland in 1996 and remained there until he moved to the Medical Protection Society to set up their Edinburgh office in 2009.

Robert is a Foundation Fellow of the Faculty of Forensic and Legal Medicine and continues to have an interest in teaching, having honorary positions at both the Universities of Glasgow and St Andrews.

Having completed his MBA at Strathclyde University Graduate Business School in 2001 he has continued to develop his business interests. In 2011 he was appointed Deputy Medical Director and in 2013 became Medical Director of the Medical Protection Society and is currently responsible for medicolegal services delivered by the Medical Protection Society to its members worldwide.

### **Prof David Isenberg** University College London



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'.





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## ISR Board members

### 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.



### 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, spondyloarthropathy and synovial inflammation. He is a member of the European Working Party on Musculoskeletal Ultrasound and the OMERACT special interest group on musculoskeletal ultrasound, previous organiser of the BSR Musculoskeletal Ultrasound course and is Faculty member of the EULAR Musculoskeletal ultrasound course. He has served as a Board member of the Irish Osteoporosis Society, as 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.



**ISR AUTUMN MEETING 2016**  
**15th & 16th September**  
**to be held in**  
**Kilashee Hotel, Naas**

### Dr Adrian Pendleton

Consultant Rheumatologist  
Musgrave Park Hospital, Belfast





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

frequently in paediatric populations than in adult populations. There have been reports of active tuberculosis in patients receiving Remicade. Patients should be evaluated for active or latent tuberculosis before Remicade treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active tuberculosis is diagnosed, Remicade therapy must not be initiated. If latent tuberculosis is diagnosed, treatment with anti-tuberculosis therapy must be initiated before initiation of Remicade. Patients on Remicade treatment should be advised to seek medical advice if symptoms of tuberculosis appear. An invasive fungal infection such as aspergillosis, candidiasis, pneumocystosis, histoplasmosis, coccidioidomycosis or blastomycosis should be suspected in patients if a serious systemic illness is developed, a physician with expertise in the diagnosis and treatment of invasive fungal infections should be consulted at an early stage. Patients with fistulising CD and acute suppurative fistulas must not initiate Remicade therapy until possible source of infection is excluded. **Hepatitis B (HBV) reactivation:** Reactivation of HBV occurred in patients receiving Remicade who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Remicade. **Hepatobiliary events:** Very rare cases of jaundice and non-infectious hepatitis, some with features of autoimmune hepatitis have been observed. Isolated cases of liver failure resulting in liver transplantation or death have occurred. **Vaccinations:** It is recommended that live vaccines not be given concurrently. Prior to initiating Remicade therapy it is recommended that paediatric patients be brought up to date with all vaccinations. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Remicade and is positive for antibodies against double-stranded DNA, treatment must be discontinued. **Neurological events:** Anti-TNF $\alpha$  agents have been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and risks of anti-TNF treatment should be carefully considered before initiation of Remicade therapy. Discontinuation of Remicade should be considered if these disorders develop. **Malignancies and lymphoproliferative disorders:** A risk of the development of lymphomas and other malignancies in patients (including children and adolescents) cannot be excluded. Caution is advised in patients with history of malignancy and in patients with increased risk for malignancy due to heavy smoking. Rare postmarketing cases of hepatosplenic T-cell lymphoma have been reported which were usually fatal. Most Remicade cases have occurred in patients with CD or UC treated concurrently with AZA or 6-MP. Caution should be exercised in patients with PSA and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Patients with UC at increased risk for, or with a prior history of dysplasia or colon carcinoma should be screened for dysplasia before therapy and at regular intervals throughout their disease course. Melanoma and Merkel cell carcinoma have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart failure:** Remicade should be used with caution in patients with mild heart failure (NYHA class I/II) and discontinued in case of new or worsening symptoms of heart failure. **Others:** Patients requiring surgery whilst on Remicade therapy should be closely monitored for infections. **Haematologic reactions:** Discontinuation of Remicade therapy should be considered in patients with confirmed significant haematologic abnormalities, including pancytopenia, leucopenia, neutropenia and thrombocytopenia. **Special populations:** Particular attention should be paid when treating the elderly (>65 years) due to a greater incidence of serious infections seen in Remicade treated patients. Some of these had a fatal outcome. **Interactions:** No interaction studies have been performed. Combination of Remicade with other biological therapeutics used to treat the same conditions as Remicade, including anakinra and abatacept is not recommended. It is recommended that live vaccines and therapeutic infectious agents should not be given concurrently with Remicade. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Remicade treatment. Administration of Remicade is not recommended during pregnancy or breast-feeding. Administration of live vaccines to infants exposed to infliximab in utero is not recommended for the months following the mother's last infliximab infusion during pregnancy. Effects of infliximab on fertility and general reproductive function are unknown. **Side-effects:** **Very Common >1/10:** Viral infection, headache, upper respiratory tract infection, sinusitis, abdominal pain, nausea, infusion related reaction, pain. **Common >1/100 to <1/10:** Bacterial infections, neutropenia, leucopenia, anaemia, lymphadenopathy, allergic respiratory symptom, depression, insomnia, vertigo, dizziness, hypoaesthesia, paraesthesia, conjunctivitis, tachycardia, palpitation, hypotension, hypertension, ecchymosis, hot flush, flushing, lower respiratory tract infection, dyspnoea, epistaxis, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, hepatic function abnormal, transaminases increased, new onset or worsening psoriasis including pustular psoriasis (primarily palm & soles), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, acroecma, alopecia, arthralgia, myalgia, back pain, urinary tract infection, chest pain, fatigue, fever, injection site reaction, chills and oedema. In phase 3 clinical studies, 18% of infliximab-treated patients compared with 5% of placebo-treated patients experienced an infusion related reaction. In post-marketing spontaneous reporting, infections are the most common serious adverse events. The most frequently reported opportunistic infections with a mortality rate of >5% include pneumocystosis, candidiasis, listeriosis and aspergillosis. **Other less common and rarely reported side effects are listed in the SPC. Overdose:** No cases of overdose have been reported. Single doses up to 20 mg/kg have been administered without toxic effects. **Package Quantities:** Type I vials, with rubber stoppers and aluminium crimp caps protected by plastic caps, containing a lyophilised powder (infliximab, 100mg). **Legal Category:** POM. **Marketing Authorisation Number:** EU/1/99/116/001. **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands. **Adverse events should be reported to MSD (Tel: 01-2987890).** Date of Revision: June 2014. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). © Merck Sharp & Dohme Ireland (Human Health) Limited, 2014. All rights reserved. Date of preparation: March 2015.

Adverse events should be reported. Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to MSD (Tel: 01-2987890).



**MSD**

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





#### 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 Orla Killeen

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



#### Dr Eamonn Molloy

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



#### Dr John Stack (SPR Rep)

John Stack is this years SpR representative on the ISR committee. He is a 4th year rheumatology SpR currently based at Connolly Hospital Blanchardstown and has previously worked at St James Hospital, Midlands Regional Hospital Mullingar and Cork University Hospital. He is a graduate of University College Cork.



#### Dr Clare Matthews

Consultant Rheumatologist  
Ulster Hospital, Belfast



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**AbbVie Ltd**  
**MSD Ireland Ltd**  
**Novartis Ireland Ltd**  
**Pfizer Healthcare Ireland**  
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**Lily UK**  
**Swedish Orphan Biovitrum Ltd**  
**UCB (Pharma) Ireland Ltd**

**The Pharmas listed above have all  
supported this meeting through a payment  
to exhibit a stand. They have had no  
involvement in any other aspect  
of this meeting.**



## Introducing Cosentyx®

- Discover a new way to treat psoriatic arthritis and ankylosing spondylitis with the first and only treatment to selectively target IL-17A<sup>1</sup>
- Rapid and sustained relief from signs and symptoms of SpA<sup>2-7</sup>
- 80% of biologic - naive SpA patients achieve clinical outcomes at one year<sup>2-7</sup>

# WATCH ME

SHOW MY FAMILY THAT I CAN STILL BE MYSELF.

 **Cosentyx**®  
secukinumab

LIFE IN MOTION

**ABBREVIATED PRESCRIBING INFORMATION.** ▼ **COSENTYX** 150 mg solution for injection in pre-filled pen. This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** COSENTYX 150 mg solution for injection in pre-filled pen. **Therapeutic Indications:** The treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; the treatment, alone or in combination with methotrexate (MTX), of active psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate. **Dosage & Method of Administration:** **Plaque Psoriasis:** Recommended dose in adults is 300 mg given as two subcutaneous injections of 150 mg. Dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. **Ankylosing Spondylitis:** The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. **Psoriatic Arthritis:** For patients with concomitant moderate to severe plaque psoriasis or who are anti TNFα inadequate responders, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For all other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. For all of the above indications, available data suggest that a clinical response is usually achieved within 16 weeks of treatment. Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 16 weeks. The safety and efficacy in children below the age of 18 years have not yet been established. **Contraindications:** Severe hypersensitivity reactions to the active substance or to any of the excipients. Clinically important, active infection (e.g. active tuberculosis). **Warnings/Precautions:** **Infections:** Cosentyx has the potential to increase the risk of infections. Infections observed in clinical studies are mainly mild or moderate upper respiratory tract infections such as nasopharyngitis not requiring treatment discontinuation. Non serious mucocutaneous candida infections more frequently reported for secukinumab than placebo in psoriasis clinical studies. Caution in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, close monitoring and discontinue treatment until the infection resolves. Should not be given to patients with active tuberculosis. Anti tuberculosis therapy should be considered prior to initiation in patients with latent tuberculosis. **Crohn's disease:** Caution should be exercised when prescribing to patients with Crohn's disease as exacerbations of Crohn's disease, in some cases serious, were observed in clinical studies. Close monitoring of patients with Crohn's disease treated with Cosentyx. **Hypersensitivity reactions:** In clinical studies, rare cases of anaphylactic reactions have been observed in patients receiving Cosentyx. If an anaphylactic or other serious allergic reactions occur, administration should be discontinued immediately and appropriate therapy initiated. **Latex-sensitive individuals:** The removable cap of the Cosentyx pre filled pen contains a derivative of natural rubber latex. **Vaccinations:** Live vaccines should not be given concurrently with Cosentyx. Patients may receive concurrent inactivated or non live vaccinations. **Concomitant immunosuppressive therapy:** Use in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. **Interactions:** Live vaccines should not be given concurrently with Cosentyx. No interaction studies have been performed in humans. A clinically relevant effect on CYP450 substrates with a narrow therapeutic index, where the dose is individually adjusted (e.g. warfarin) cannot be excluded. Therapeutic monitoring should be considered on initiation in patients treated with these types of medicinal products. No interaction seen when administered concomitantly with methotrexate (MTX) and/or corticosteroids. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. It is preferable to avoid the use of Cosentyx in pregnancy as there are no adequate data from the use of secukinumab in pregnant women. It is not known whether secukinumab is excreted in human milk. A decision on whether to discontinue breast feeding during treatment and up to 20 weeks after treatment or to discontinue therapy with Cosentyx must be made taking into account the benefit of breast feeding to the child and the benefit of Cosentyx therapy to the woman. The effect of secukinumab on human fertility has not been evaluated. **Undesirable Effects:** **Very common** (≥1/10): Upper respiratory tract infections. **Common** (≥1/100 to <1/10): Oral herpes, rhinorrhoea, diarrhoea, urticaria. **Uncommon** (≥1/1,000 to <1/100): Oral candidiasis, tinea pedis, otitis externa, neutropenia, conjunctivitis. **Rare** (≥1/10,000 to <1/1,000): Anaphylactic reactions. Please see Summary of Product Characteristics for further information on undesirable effects. **Legal Category:** POM. **Marketing Authorisation Holder:** Novartis Europharm Ltd, Frimley Business Park, Camberley, GU16 7SR, United Kingdom. **Marketing Authorisation Numbers:** EU/1/14/080/004-005. **Date of Revision of Abbreviated Prescribing Information:** November 2015. Full prescribing information is available upon request from: Novartis Ireland Limited, Vista Building, Elm Park Business Park, Elm Park, Dublin 4. Tel: 01-2204100 or at [www.medicines.ie](http://www.medicines.ie). Detailed information on this product is also available on the website of the European Medicines Agency <http://www.ema.europa.eu>. **References:** 1. Cosentyx Summary of Product Characteristics, November 2015. 2. Novartis Data on File 2015. MEASURE 2 Clinical Study Report. 3. Baeten D, et al. Arthritis Rheum 2015; 67 (S10): 3482. Poster 2890 at the American College of Rheumatology (ACR), 10 November 2015, San Francisco, USA. 4. Molnes IB et al. Lancet 2015; 386: 1137-46. 5. Kavanaugh A, et al. Ann Rheum Dis 2015; 74 (S2): 345-6. Poster THU0411 at European League Against Rheumatology (EULAR), 10 June 2015, Rome, Italy. 6. Kavanaugh A, et al. Arthritis Rheum 2015; 67 (S10): 2573. Abstract 2146 at the American College of Rheumatology (ACR), 9 November 2015, San Francisco, USA. 7. Novartis Data on File 2015. FUTURE 2 Clinical Study Report. **Date of Preparation:** February 2016. IE02/COS16-CNF010a

 **NOVARTIS**  
PHARMACEUTICALS





Irish Rheumatology Health  
Professionals Society

## IRHPS Spring 2016 Update

### Welcome to the Spring Conference 2016

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

We had a very successful meeting in Naas last September with presentations from Colin Dunleavy, Mary Ryan and Natalie Wallace all from the Weight Management Service in St. Columcille's Hospital, Loughlinstown, Co. Dublin. The two highest scoring IRHPS abstract submissions also presented their work. Congratulations to Rachel Burke, Senior Physiotherapist, Naas, winner of the Professor Barry Bresnihan gold medal award and Oriel Corcoran, Clinical Specialist Occupational Therapist, U.H.W. who claimed the silver prize. Other awards included the Roche poster awards. The prize winners were Jennifer Ashton and Aisling Brennan who have won the opportunity to attend EULAR in London 2016. The UCB poster award winners were Tom O 'Dwyer, Paul Kirwan, Stephanie Naromoor, Maria McGrath and Una Martin. The people's choice award also went to Una Martin. This year's BSR winners were Karen Quinn and Derek Deely. Congratulations to Louise Larkin, PhD candidate, University of Limerick who was successfully awarded the Janssen Education Bursary in 2015.

I would like to take this opportunity to welcome the IRHPS incoming chair Eileen Shinnors from Our Lady's Hospice and Care Service Harolds Cross. Remember Health Professionals this is your society and if you have topics you would like covered in future meetings please contact us. Also keep an eye on our website [www.irhps.ie](http://www.irhps.ie) for news on meetings and educational opportunities.

Best wishes,  
**DEREK DEELY**  
IRHPS Chair



# A unique mechanism of action to treat active psoriatic arthritis



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

## STELARA® solution for injection PRESCRIBING INFORMATION.

**ACTIVE INGREDIENT(S):** Ustekinumab. Please refer to Summary of Product Characteristics (SmPC) before prescribing. **INDICATION(S):** **Plaque psoriasis adults:** Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA. **Plaque psoriasis paediatrics:** Moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. **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. Self-injecting patients or caregivers ensure appropriate training. Physicians are required to follow-up and monitor patients. **Plaque psoriasis, adults & elderly:** Patients <100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients >100 kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients). **Plaque psoriasis paediatrics (12 years and older):** Patients <60 kg, 0.75 mg/kg at week 0, followed by 0.75 mg/kg at week 4 then every 12 weeks thereafter. Patients ≥60-100kg, 45 mg at week 0 followed by 45 mg at week 4, then every 12 weeks. Patients >100 kg, 90mg at week 0, followed by 90mg at week 4, then every 12 weeks. **Psoriatic arthritis, adults & elderly:** 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Alternatively, 90 mg may be used in patients with a body weight >100 kg. Consider discontinuation if no response after 28 weeks. **Children <12 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. **Latex sensitivity:** Needle cover contains natural rubber (latex), may cause allergic reactions. **Immunotherapy:** Not known whether STELARA affects allergy immunotherapy. **Serious skin conditions:** Exfoliative dermatitis has been reported following treatment. Discontinue STELARA if a drug reaction is suspected. **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), skin exfoliation, exfoliative dermatitis. Studies show adverse events reported in ≥12 year olds with plaque psoriasis were similar to those seen in previous studies in adults with plaque psoriasis. **Refer to SmPC for other side effects.** **FERTILITY:** The effect of ustekinumab has not been evaluated. **PREGNANCY:** Should be avoided. Women of childbearing potential: Use effective contraception during treatment and for at least 15 weeks post-treatment. **LACTATION:** Limited data in humans. **INTERACTIONS:** *In vitro*, STELARA had no effect on CYP450 activities. **Vaccinations:** Live vaccines should not be given concurrently with STELARA, and should be withheld for at least 15 weeks after last dose of STELARA. STELARA can resume at least 2 weeks after such vaccinations. No data on secondary transmission of infection by live vaccines

in patients receiving STELARA. **Concomitant immunosuppressive therapy:** Psoriasis: The safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. **Refer to SmPC for full details of interactions.** **LEGAL CATEGORY:** Prescription Only Medicine. **PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER:** 45 mg: 1 x vial. EU/1/08/494/001, 45mg: 1 x 0.5ml pre-filled syringe, EU/1/08/494/003. 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 2015

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

Prescribing information last revised: 06/2015

References: 1. Stelara Summary of Product Characteristics, available at [www.medicines.ie](http://www.medicines.ie)

Date of preparation: March 2016 | PHIR/STE/0913/0002a(1)a(1)







### ISR Presidents

**Dr Sandy Fraser** 2016 – present  
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**Prof D. Kane** 2014 – 2016  
Dublin

**Dr G. Wright** 2012 – 2014  
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**Prof Gaye Cunnane** 2010 – 2012  
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**Dr R. Kavanagh** 2008 - 2010  
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**Dr J. Lee** 2006 - 2008  
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**Dr A. Bell** 1996 – 1998  
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**Prof B. Bresnihan** RIP  
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**Prof M. Molloy** 1992 – 1994  
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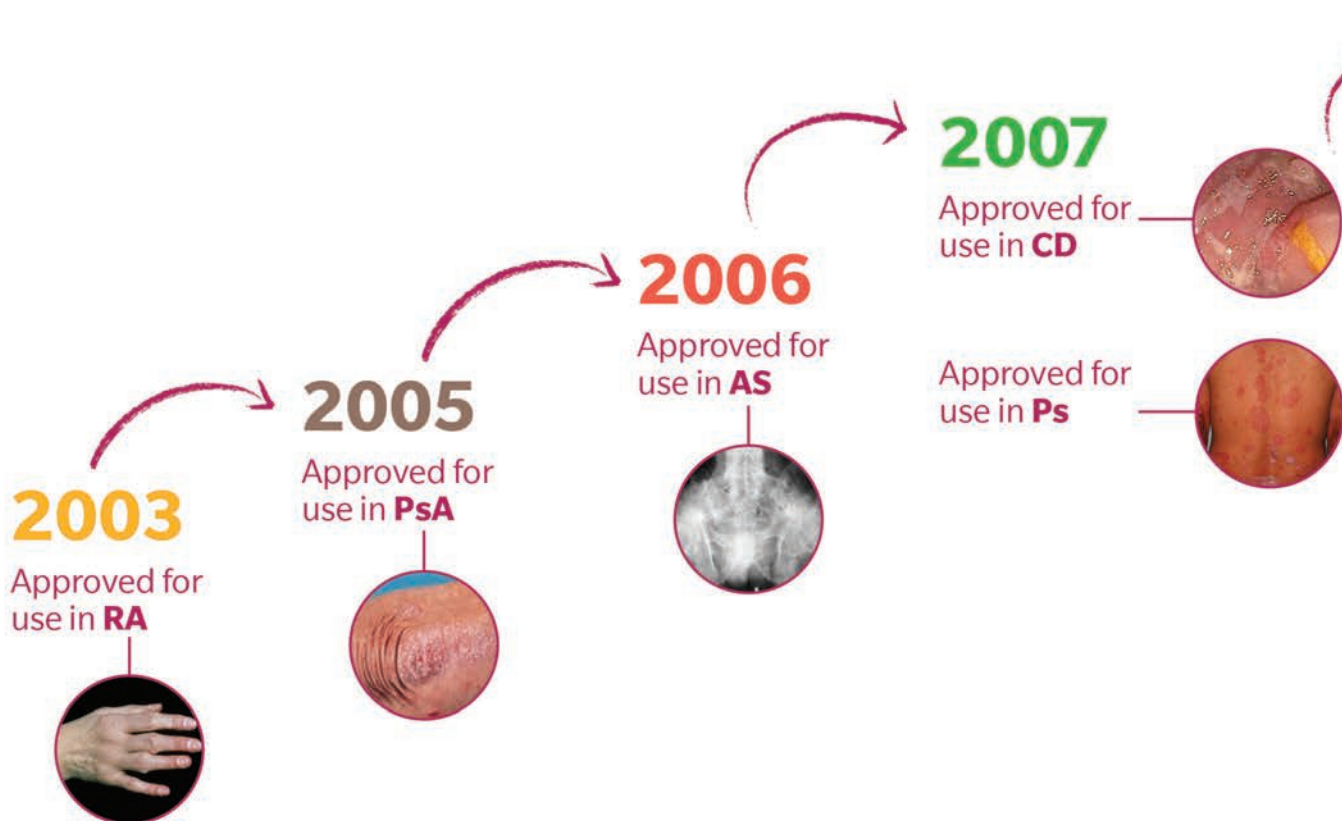
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Consultant Rheumatologist  
Musgrave Park Hospital, Belfast



# Trust in HUMIRA

HUMIRA has 12 approved indications<sup>1</sup>



## Rheumatoid Arthritis (RA)

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.

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

HUMIRA 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.

## Psoriatic Arthritis (PsA)

HUMIRA is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. HUMIRA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

## Ankylosing Spondylitis (AS)

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

## Crohn's Disease (CD)

HUMIRA is indicated for treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

Date of Preparation: August 2015 IREHUM140419a(2)





### Psoriasis (Ps)

HUMIRA is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

### Polyarticular juvenile idiopathic arthritis

HUMIRA in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). HUMIRA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. HUMIRA has not been studied in patients aged less than 2 years.

### Paediatric Crohn's Disease (Paed CD)

HUMIRA is indicated for the treatment of severe active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.

### Hidradenitis Suppurativa (HS)

HUMIRA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

### Paediatric plaque psoriasis (Paed Ps)

Treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age with an inadequate response to or who are inappropriate candidates for topical therapy and phototherapies.

### Ulcerative Colitis (UC)

HUMIRA is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

### Axial Spondyloarthritis Without Radiographic Evidence of AS (nr-axSpA)

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.

### Enthesitis-related Arthritis (ERA)

HUMIRA is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Full prescribing information is available upon request from AbbVie Limited, Immunology Division, 14 Riverwalk, Citywest Business Campus, Dublin 24, D24 XN32.

**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 4UB, UK.

**Reference:** 1. HUMIRA [summary of product characteristics]. AbbVie Ltd.

 **HUMIRA**<sup>®</sup>  
adalimumab  
*destination you*<sup>™</sup>





## Join the Arthritis Ireland team for the 2016 Women's Mini Marathon on June 6<sup>th</sup> in Dublin.

Raise badly needed funds so that we can continue to provide support, information & services to those living with arthritis and their families.

Register today at the Arthritis Ireland stand, visit [www.arthritisireland.ie](http://www.arthritisireland.ie) or call Orla on 01-647 0209 to receive your pack.



Join our team of doctors, researchers and patients and cycle 100km to help find a cure for arthritis.

Take part in this years **Working on a Cure Cycle** in Wicklow on June 12<sup>th</sup> and raise vital funds to support ongoing research.

Register today at the Arthritis Ireland stand, visit [www.arthritisireland.ie](http://www.arthritisireland.ie) or call Orla on 01-647 0209 to receive your pack.



**WORKING ON A CURE CYCLE**





UCB Stand



MSD Stand



Prof Trevor Duffy at Roche stand



Dr Suzanne Donnelly and Dr Sandy Fraser at Menarini Stand



BMS Stand



AbbVie Stand



Grunenthal Stand



Celgene Stand



# Adenuric<sup>®</sup>

(febuxostat)

## Treat to target. Daily.<sup>1,2</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. **Older people:** No dose adjustment required. **Renal impairment:** No dosage adjustment necessary in patients with mild or moderate renal impairment. Efficacy and safety not fully evaluated in patients with severe renal impairment. **Hepatic impairment:** Recommended dosage in patients with mild hepatic impairment is 80 mg. Limited information available in patients with moderate hepatic impairment. Efficacy and safety has not been studied in patients with severe hepatic impairment. **Children and adolescents:** Safety and efficacy in children under 18 has not been established. **Organ transplant recipients:** No experience therefore not recommended. **Contraindications:** Hypersensitivity to the active ingredient or to any of the excipients. **Warnings and precautions:** **Cardio-vascular disorders:** **Not recommended in patients with ischaemic heart disease or congestive heart failure.** **Product allergy/hypersensitivity:** Advise patients of signs/symptoms of allergic/hypersensitivity reactions and monitor closely for symptoms. Stop treatment immediately if serious reactions occur, including Stevens-Johnson syndrome, Toxic epidermal necrolysis and acute anaphylactic reaction/shock; do not re-start febuxostat at any time. Severe hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with fever, haematological, renal or hepatic involvement in some cases. **Acute gouty attacks (gout flare):** Do not start treatment until an acute attack of gout has completely subsided. As with other urate lowering medicinal products, gout flares may occur during initiation of treatment. At treatment initiation flare prophylaxis for at least 6 months with an NSAID or colchicine is recommended. If a gout flare occurs during treatment, do not discontinue. Manage the gout flare concurrently as appropriate. Continuous treatment decreases frequency and intensity of gout flares. **Xanthine deposition:** As with other urate lowering medicinal products, in patients in whom the rate of urate formation is greatly increased (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome), the absolute concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract. As there has been no experience of treating gout in these patients with febuxostat such use is not recommended. **Mercaptopurine/azathioprine:** Not recommended in patients concomitantly treated with mercaptopurine/azathioprine. Where combination cannot be avoided, monitor patients closely. Dose reduction for mercaptopurine/azathioprine is recommended. **Theophylline:** No pharmacokinetic interaction shown with febuxostat 80 mg, no data for 120 mg. **Liver disorders:** Liver function test is recommended prior to the initiation of therapy and periodically thereafter based on clinical judgement. **Thyroid disorders:** Caution in patients with alteration of thyroid function. **Lactose:** Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** **Mercaptopurine/azathioprine:** On the basis of the mechanism of action of febuxostat on xanthine oxidase inhibition concomitant use is not recommended. No data is available regarding the safety of febuxostat during cytotoxic chemotherapy. **Rosiglitazone/CYP2C8 inhibitors:** No dosage adjustment required. **Theophylline:** No special caution advised for 80 mg febuxostat, no data available for 120 mg. **Naproxen and other inhibitors of glucuronidation:** Can be co-administered with naproxen with no dose adjustments necessary. **Inducers of glucuronidation:** Monitoring of serum uric acid is recommended 1-2 weeks after start of treatment with a potent inducer of glucuronidation. Cessation of treatment of an inducer might lead to increased plasma levels of febuxostat. **Colchicine/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\*\*, liver injury\*\*, Toxic epidermal necrolysis\*\*, Stevens-Johnson Syndrome\*\*, DRESS\*\*, angioedema\*\*, generalized rash (serious)\*\*, erythema, exfoliative rash, rash follicular, rash vesicular, rash pustular, rash pruritic\*\*, rash erythematous, rash morbilliform, alopecia, hyperhidrosis, rhabdomyolysis\*\*, joint stiffness, musculoskeletal stiffness, tubulointerstitial nephritis\*\*, micturition urgency, thirst, blood glucose increase, activated partial thromboplastin time prolonged, red blood cell count decrease, blood alkaline phosphatase increase. \*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:** May 2015.

**References:** 1. Adenuric 80 mg SmPC, February 2014. 2. Adenuric 120 mg SmPC, April 2015.

ADENURIC<sup>®</sup> is a trademark of Teijin Limited, Tokyo, Japan

Date of item: May 2015  
IR-ADEN-03a-2015



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Healthcare for Life





Keynote Speakers from St. Columcille's Hospital with some of the IRHPS Committee



EULAR winners Jennifer Ashton and Aisling Brennan



Professor Barry Bresnihan Award Winners



Cara McDonagh receiving Young Investigator Award from Prof David Kane and Dr Julian Maitland Med Dir UCB



Dr Sinead Harney Hon Treasurer of ISR



# Efficacy still going strong five years on

monthly  
**Simponi**<sup>®</sup>  
golimumab



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



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



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

## SIMPONI<sup>®</sup> 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN SIMPONI<sup>®</sup> 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (GOLIMUMAB)

**Prescribing Information** (Refer to full SPC text before prescribing Simponi (golimumab))

**Indications:** Rheumatoid Arthritis (RA): Simponi, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; Psoriatic Arthritis (PsA): Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. Ankylosing Spondylitis (AS): Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. Non-radiographic axial spondyloarthritis (nr-Axial SpA): Simponi is indicated for the treatment of severe, active nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. Ulcerative colitis (UC): Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Dosage and administration:** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA or UC. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. RA: Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. PsA: Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. AS and nr-Axial SpA: Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. UC: Patients weighing < 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks. Patients weighing ≥ 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). Missed dose: If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. Older patients (≥ 65 years): no dose adjustment required. Paediatric patients (<18 years) and patients

with renal and hepatic impairment: Simponi is not recommended in these populations. **Contraindications:** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. **Hepatitis B (HBV) reactivation:** Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi. **Malignancies and lymphoproliferative disorders:** Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6 mercaptopurine (6-MP). The potential risk with the combination of AZA or 6 MP and Simponi should be carefully considered. A risk for the development for HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma (all TNF-blocking agents including Simponi) and Merkel cell carcinoma (other TNF-blocking agents) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart Failure:** Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. **Neurological events:** Use of anti-TNF therapy,



## The GO studies

Recently presented five-year data confirm good persistence, sustained efficacy and predictable tolerability across indications with Simponi<sup>1-3</sup>

Persistence with  
Simponi at 5 years

(Simponi 50mg and 100mg)



GO-FORWARD<sup>1</sup>

70%

n=444



GO-REVEAL<sup>2</sup>

69%

n=405



GO-RAISE<sup>3</sup>

71%

n=356

including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. **Surgery:** Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. **Haematological reactions:** There have been post-marketing reports of pancytopenia, leukopenia, neutropenia, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers. Cytopenias including pancytopenia have been reported infrequently in clinical trials. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents:** It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. **Allergic reactions:** If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations:** Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the re-Axial SpA study. **Excipients:** Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **Interactions:** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **Pregnancy and Lactation:** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **Side-effects: Refer to SmPC for complete information on side effects** Very Common (≥ 1/10): upper respiratory tract infection; Common (≥ 1/100): bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma\*, hepatosplenic T-cell lymphoma\*, leukopenia, thrombocytopenia, pancytopenia, aplastic anaemia, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. \*Observed with other TNF-blocking agents, but not

observed in clinical studies with golimumab **Package quantities:** 1 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection or 1 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection or 1 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection. **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number:** 50 mg Pre-filled Pen EU/1/09/546/001; 50 mg Pre-filled Syringe EU/1/09/546/003; 100 mg Pre-filled Pen EU/1/09/546/005. **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands. **Date of Revision of Text:** December 2015. **Further information is available on request from:** MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). **Date of preparation:** March 2016.

Adverse events should be reported. Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to MSD (Tel: 01-299 8700)

### References

1. Keystone EC, et al. *J Rheumatol*. 2016 Feb;43(2):298-306.
2. Kavanaugh A, et al. *Ann Rheum Dis*. 2014 Sep;73(9):1689-94.
3. Deodhar A, et al. *Ann Rheum Dis*. 2015 Apr;74(4):757-61.



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# Introducing A NOVEL ORAL THERAPY THAT MAY CHANGE THE WAY YOU TREAT PSORIATIC ARTHRITIS



- ◆ Proven efficacy in clinical trials vs. placebo<sup>1</sup>
- ◆ Favourable safety profile with no increased risk of malignancy, serious infection, or tuberculosis vs. placebo, demonstrated in clinical trials<sup>1,2</sup>
- ◆ Oral dosing<sup>1</sup>
- ◆ No requirement for tuberculosis prescreening or any ongoing laboratory monitoring<sup>1,2</sup>

## INDICATION

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



**Prescribing Information:** OTEZLA® (apremilast) 10mg, 20mg and 30mg film coated-tablets.

Refer to the Summary of Product Characteristics (SPC) before prescribing.

**Presentation:** 10mg, 20mg and 30mg film coated-tablets. **Indications:** Psoriatic arthritis: OTEZLA®, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. **Psoriasis:** OTEZLA® is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA). **Dosage and administration:** Treatment with OTEZLA® should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis. The recommended dose of OTEZLA® is 30mg twice daily taken orally, morning and evening, approximately 12 hours apart, with no food restrictions. The film-coated tablets should be swallowed whole. To reduce risk of gastrointestinal symptoms, an initial dose titration is required according to the following schedule: Day 1: 10mg in morning; Day 2: 10mg in morning and 10mg in evening; Day 3: 10mg in morning and 20mg in evening; Day 4: 20mg in morning and 20mg in evening; Day 5: 20mg in morning and 30mg in evening; Day 6 and thereafter: 30mg twice daily. No re-titration is required after initial titration. If patients miss a dose, the next dose should be taken as soon as possible. If it is close to the time for their next dose, the missed dose should not be taken and the next dose should be taken at the regular time. During pivotal trials the greatest improvement

was observed within the first 24 weeks of treatment. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment should be reconsidered. The patient's response to treatment should be evaluated on a regular basis. Clinical experience beyond 52 weeks is not available in psoriasis. **Special populations:** *Paediatric population:* The safety and efficacy of apremilast in children aged 0 to 17 years have not been established. No data are available. *Elderly patients:* No dose adjustment is required for this patient population. *Patients with renal impairment:* No dose adjustment is needed in patients with mild and moderate renal impairment. The dose of apremilast should be reduced to 30mg once daily in patients with severe renal impairment (creatinine clearance of less than 30mL per minute estimated by the Cockcroft-Gault equation). For initial dose titration in this group, it is recommended that OTEZLA® be titrated using only the morning doses and the evening doses be skipped. *Patients with hepatic impairment:* No dose adjustment is necessary for patients with hepatic impairment. **Contraindications:** Hypersensitivity to the active substance(s) or to any of the following excipients: Microcrystalline cellulose, Lactose monohydrate, Croscarmellose sodium, Magnesium stearate, Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, Iron oxide red (E172). The 20mg tablets also contain iron oxide yellow (E172). The 30mg tablets also contain iron oxide yellow (E172) and iron oxide black (E172). OTEZLA® is contraindicated in pregnancy and should be excluded before treatment can be initiated. **Special warnings and precautions:** Patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. OTEZLA® should be dose reduced to 30mg once daily in patients with severe renal impairment. Apremilast

may cause weight loss. Patients who are underweight at the start of treatment should have their body weight monitored regularly. In the event of unexplained and clinically significant weight loss, these patients should be evaluated by a medical practitioner and discontinuation of treatment should be considered. Women of childbearing potential should use an effective method of contraception to prevent pregnancy during treatment. Apremilast should not be used during breast-feeding. No fertility data is available in humans. **Interactions:** Co-administration of strong cytochrome P450 3A4 (CYP3A4) enzyme inducer, rifampicin, resulted in a reduction of systemic exposure of apremilast, which may result in a loss of efficacy of apremilast. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with apremilast is not recommended. In clinical studies, apremilast has been administered concomitantly with topical therapy (including corticosteroids, coal tar shampoo and salicylic acid scalp preparations) and UVB phototherapy. There was no clinically meaningful drug-drug interaction between ketoconazole and apremilast. Apremilast can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between apremilast and methotrexate in psoriatic arthritis patients. Apremilast can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between apremilast and oral contraceptives containing ethinyl estradiol and norgestimate. Apremilast can be co-administered with oral contraceptives. **Side effects:** The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache,

and tension headache. The most common adverse reactions leading to discontinuation during the first 16 weeks of treatment were diarrhoea, and nausea. The overall incidence of serious adverse reactions was low and did not indicate any specific system organ involvement. Prescribers should consult the summary of product characteristics in relation to other side-effects. **NHS list price:** £265.18 per 14 day titration pack; £550 per pack of 56 tablets (30mg). **Legal category:** POM. **Marketing authorisation numbers:** EU/1/14/981/001, EU/1/14/981/002 and EU/1/14/981/003. **Marketing authorisation holder:** Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom. **Date of preparation:** January 2015. **Approval code:** UK-18140098.

Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk). Adverse events should also be reported to Celgene Drug Safety Tel: 0800 238 9908; Fax: 0844 801 0468

**References:**  
1. OTEZLA Summary of Product Characteristics available at [www.medicines.org.uk](http://www.medicines.org.uk)  
2. Mease PJ, et al. Poster 310 presented at the Annual Meeting of ACR/ARHP, San Diego, California, October 26-30, 2013.  
**Date of Preparation:** February 2015 UK-18140071b





Dr Ursula Fearon Researcher SVUH



Dr Michelle Trenkman, UCD



Dr Richard Conway, UCD



Prof Fergus Shanahan CUH



Dr Sureth Rattan, Aarhus Univ. Denmark



Dr Gary Wright & Dr Ronan Mullan



Dr Cara McDonagh Winner of Young Investigator Award



Prof David Kane Presenting Life Time Achievement Award to Dr Aubrey Bell



Prof David Kane, Dr Gary Wright, Mrs Rose Bell & Dr Aubrey Bell



# CIMZIA® : making a difference... ...to patients' lives

**cimzia**  
(certolizumab pegol)

Rapid and sustained response from **week 1** in RA, PsA and AxSpA.<sup>1, 2, 3, 4</sup>

## Early Rheumatoid Arthritis

Early rheumatoid arthritis: Cimzia®, in combination with methotrexate (MTX), is indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs.<sup>1</sup>



Hannah - Early RA

"I want to be able to plan for the future and commit to my career path"

- Hannah, 25 years old, Policewoman\*

## Rheumatoid Arthritis

Rheumatoid arthritis: Cimzia®, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate, has been inadequate.<sup>1</sup>



Kate - RA

"I want reassurance that things are going to get better"

- Katie, 51 years old, Nurse\*

## Psoriatic Arthritis

Psoriatic arthritis: Cimzia®, in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate.<sup>1</sup>



Lucy - PsA

"I just want to feel normal again, as soon as possible"

- Lucy, 36 years old, Cafe Worker\*

## Axial Spondyloarthritis

Axial spondyloarthritis: Cimzia®, is indicated for the treatment of adult patients with severe active axial spondyloarthritis.<sup>1</sup>



Matt - AxSpA

"I need rapid relief from back pain so I can get back to work"

- Matt, 35 years old, PE Teacher\*

\*Patient profiles and quotes are for illustration purposes only.

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Further information is available from: UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE. Tel: +44 (0)1753 534655. Fax: +44 (0)1753 536632.  
UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, City West Road, Dublin 24, Ireland. Tel: +353 14637395 Fax: +353 14637396  
Email: medicalinformationuk@ucb.com. Legal Category: POM.

1. CIMZIA® Summary of Product Characteristics. 2. Mease PJ, Fleischmann R, Deodhar AA, Wollenhaupt J, Khraishi M, Kielar D, et al. Effect of certolizumab pegol on signs and symptoms in patients with psoriatic arthritis: 24-week results of a Phase 3 double-blind randomised placebo-controlled study (RAPID-PsA). Ann Rheum Dis. 2014;73(1):48-55. 3. Landewé R, Braun J, Deodhar A, Dougados M, Maksymowych WP, Mease PJ, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. Ann Rheum Dis. 2014;73(1):39-47. 4. Keystone E, Heijde D, Mason D, Jr., Landewé R, Vollenhoven RV, Combe B, et al. Certolizumab pegol plus methotrexate is significantly more effective than placebo plus methotrexate in active rheumatoid arthritis: findings of a fifty-two-week, phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. Arthritis Rheum. 2008;58(11):3319-29.

Further information is available in the Cimzia SmPC.



# ISR Autumn 2015



Prof David Kane making Presentation to Dr Gary Wright on his retirement from board of ISR



Dan Duffy AbbVie, Dr Sureth Rattan Denmark & Dr Len Harty CUH



Dr John Stack MMUH & Dr Barry O'Shea SJH



Dr Andrew Kerins, Professor David Kane & Dr Adrian Pendleton



Dr Eamon Molloy SVUH & Dr Shawn Chavrimatoo



Mrs Rosie Bell, dr Aubrey Bell, Dr Esme Whitehead & Dr Bobby Coughlan



Dr Philip Gardiner & Dr Darragh Foley-Nolan



Dr Alex McGregor, Prof Gaye Cunnane, Dr Carmel Silke



# TAPENTADOL PALEXIA® SR

## ...A KEY FOR CHRONIC PAIN



## FOR SEVERE CHRONIC PAIN

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



#### PALEXIA SR® PROLONGED RELEASE TABLETS PRESCRIBING INFORMATION

Refer to the Summary of Product Characteristics (SmPC) before prescribing. **PRESENTATION:** 50 mg (white), 100 mg (pale yellow), 150 mg (pale pink), 200 mg (pale orange) and 250 mg (brownish red) prolonged-release tablets contain 50 mg, 100 mg, 150 mg, 200 mg and 250 mg of tapentadol (as hydrochloride) respectively. **INDICATION:** Palexia SR is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. **DOSAGE AND METHOD OF ADMINISTRATION:** Individualise according to severity of pain, the previous treatment experience and the ability to monitor the patient. Swallowed whole with sufficient liquid, not divided or chewed, with or without food. Initial dose 50 mg twice a day. Switching from other opioids may require higher initial doses. Titrate in increments of 50 mg twice a day every 3 days for adequate pain control. Total daily doses greater than 500 mg not recommended. **Discontinuation of treatment:** Taper dose gradually to prevent withdrawal symptoms. **Renal/hepatic impairment:** Not recommended in patients with severe cases. Caution and dose adjustments with moderate hepatic impairment. **Elderly:** May need dose adjustments. Children below 18 years: Not recommended. **CONTRAINDICATIONS:** Hypersensitivity to ingredients, suspected or having paralytic ileus, acute intoxication with alcohol, hypnotics, centrally acting analgesics or psychotropics. Not for use when mu-opioid receptor agonists are contraindicated (e.g. significant respiratory depression, acute or severe bronchial asthma or hypercapnia). **SPECIAL WARNINGS AND PRECAUTIONS:** At risk patients may require monitoring due to misuse, abuse, addiction or diversion. At high doses or in mu-opioid receptor agonist sensitive patients, dose-related respiratory depression may occur. Caution and monitoring required with impaired respiratory function. Should not use in patients susceptible to intracranial effects of carbon dioxide retention (e.g. increased intracranial pressure, impaired consciousness or coma). Use with caution with head injury, brain tumours, moderate hepatic impairment, biliary tract disease including acute pancreatitis. Not recommended if history of or at risk of seizures or with severe renal or hepatic impairment. Care should be taken when combining with mixed mu-opioid agonists/antagonists (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine). Should not use with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **INTERACTIONS:** Use with benzodiazepines, barbiturates and opioid analgesics, antitussive drugs and substitutive treatments may enhance the risk of respiratory depression. Central nervous system (CNS) depressants (e.g. benzodiazepines, antipsychotics, H1-antihistamines, opioids, alcohol) can enhance the sedative effect and impair vigilance. Consider dose reduction with respiratory or CNS depressant agents. In isolated cases, serotonin syndrome has been reported with Palexia SR in combination with serotonergic medicinal products (e.g. serotonin re-uptake inhibitors). Use with strong inhibitors of uridine diphosphate transferase isoenzymes (involved in glucuronidation) may increase systemic exposure of Palexia SR. Risk of decreased efficacy or adverse events if used with strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort). Avoid use in patients who have taken monoamine oxidase inhibitors (MAOIs) within the last 14 days, due to cardiovascular events. **PREGNANCY AND LACTATION:** Use in pregnancy only if the potential benefit justifies the potential risk to the foetus. Not recommended during and immediately before labour and delivery. Do not use during breast feeding. Driving and using machines: May have major effect on ability to drive and use machines, especially at the beginning or change in treatment, in connection with alcohol or tranquilisers. **UNDESIRABLE EFFECTS:** **Very common** ( $\geq 1/10$ ): dizziness, somnolence, headache, nausea, constipation. **Common** ( $\geq 1/100$ ,  $< 1/10$ ): decreased appetite, anxiety, depressed mood, sleep disorder, nervousness, restlessness, disturbance in attention, tremor, involuntary muscle contractions, flushing, dyspnoea, vomiting, diarrhoea, dyspepsia, pruritus, hyperhidrosis, rash, asthenia, fatigue, feeling of body temperature change, mucosal dryness, oedema. Other important undesirable effects: palpitations, heart rate increased/decreased (**uncommon**  $\geq 1/1000$ ,  $< 1/100$ ), drug hypersensitivity including angioedema, anaphylaxis and anaphylactic shock (**uncommon**  $\geq 1/1000$ ,  $< 1/100$ ), respiratory depression (**rare**  $\geq 1/10,000$ ,  $< 1/1000$ ), convulsion (**rare**  $\geq 1/10,000$ ,  $< 1/1000$ ). No evidence of increased risk of suicidal ideation or suicide with Palexia SR. Additional information is available on request. **OVERDOSE:** Seek specialist treatment (see SmPC). **LEGAL CLASSIFICATION:** POM, CD (Schedule II). **MARKETING AUTHORISATION NUMBERS AND PACK SIZES:** 50 mg: PA 1189/7/4, 28 and 56 packs; 100 mg: PA 1189/7/5, 56 pack; 150 mg: PA 1189/7/6, 56 pack; 200 mg: PA 1189/7/7, 56 pack and 250 mg: PA 1189/7/8, 56 pack. **MARKETING AUTHORISATION HOLDER:** Grünenthal Ltd, Regus Lakeside House, 1 Furze Ground Way, Stockley Park East, Uxbridge, Middlesex, UB11 1BD, UK. **DATE OF PREPARATION:** November 2013. IRE/P13 0025b. **REFERENCE:** 1. Palexia SR Summary of Product Characteristics



# ISR Autumn 2015



Dr Rachel Cole & Dr Miriam O'Sullivan



Mark Bullock Guest Speaker



Prof Gerd Burmester, Berlin



Dr Eamon Molloy & Dr Sandy Fraser Incoming President of ISR



Prof Gerry Wilson SVUH



Attentive Audience



Dr Ronan Mullan, Professor David Kane & Dr Jo Kitchen



Dr Fahd A M Ashraf receiving his Poster Prize



Prof David Kane presenting Poster Prize to Dr Agnes Sventpetery



# ISR Autumn 2015



Dr Xenofon Baraliakos



Dr John Carey & Dr Claire Sheehy



Prof Doug Veale presenting cheque to John Church CEO of Arthritis Ireland



Dr Carl Orr receiving his Oral Prize



Dr Len Harty receiving his Poster Prize



Dr Sandy Fraser incoming President ISR and Dr John Carey NUIG.



Dr Michelle Doran, Prof Oliver Fitzgerald & Dr Frances Stafford



Dr Roger Stewart Receiving his Oral Prize



Eva McCabe Receiving Bernard Connor Medal from Prof David Kane





Transforming lives<sup>1</sup>

15 years  
of clinical  
trials  
and real world  
experience<sup>1</sup>

1<sup>st</sup> EMA-  
approved  
anti-TNF  
in RA<sup>17</sup>

More than  
350  
trials<sup>18</sup>

4 Over  
million  
patient-years  
of collective  
clinical experience<sup>11</sup>

1 Over  
million  
patients  
treated<sup>10</sup>

More than  
5700  
publications<sup>19</sup>

of partnership and experience<sup>1</sup>  
15  
years



#### ABBREVIATED PRESCRIBING INFORMATION

##### Enbrel<sup>®</sup>

##### etanercept

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

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

**European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **Legal Category:** S1A. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. **For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact:** Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **API Reference Number:** EN 8\_0. **Pfizer number:** 2013-0003980. **Date of Prescribing Information:** July 2014.

† Across all indications.

**References:** 1. Scott LJ. Drugs. 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. November 2015. 3. Humira Summary of Product Characteristics. November 2015. 4. Remicade Summary of Product Characteristics. September 2015. 5. Cimzia Summary of Product Characteristics. December 2015. 6. Simponi Summary of Product Characteristics. November 2015. 7. Remicade EMA report 8. <http://clinicaltrials.gov>. Accessed 12 Nov 2014. 9. [www.pubmed.org](http://www.pubmed.org). Accessed 12 Nov 2014. 10. Data on file. January 2015. 11. Data on file. March 2014.

Date of preparation: March 2016. PP-ENB-IRL-0004



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

THINK RoACTEMRA<sup>1</sup>



NOW  
AVAILABLE IN  
SUBCUTANEOUS (SC)

**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 (RoActemra IV) and RoActemra<sup>®</sup> 162mg solution for injection in pre-filled syringe (RoActemra SC).** Indications: **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 (RoActemra IV) and RoActemra<sup>®</sup> 162mg solution for injection in pre-filled syringe (RoActemra SC).** Indications: **RoActemra SC:** 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 disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients  $\geq 2$  years of age, who responded inadequately to previous therapy with NSAIDs and systemic corticosteroids, (iv) juvenile idiopathic polyarthritis (pJIA) (rheumatoid factor positive or negative and extended oligoarthritis) in patients  $\geq 2$  years of age, who responded inadequately to previous therapy with MTX. RoActemra IV/SC can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. RoActemra IV/SC has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX for the treatment of adult RA patients. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. **RA:** RoActemra IV: 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients  $>100$ kg, doses  $>800$ mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Rotate injection site frequently. **sJIA (RoActemra IV only):** Patients  $<2$  years of age – no data. Patients  $>2$  years, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 12mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients  $<2$  years of age – no data. Patients  $>2$  years of age, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 10 mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. Dose adjustments: For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). **Special Populations:** No data available for RoActemra SC in patients  $<18$  years of age. Closely monitor renal function in patients with moderate to severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients  $>65$  years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Patients to seek medical attention if signs/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment even if they have received premedication with steroids and anti-histamines. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. Not recommended in patients with baseline ALT or AST  $> 5 \times$  ULN; caution in patients with ALT or AST  $> 1.5 \times$  ULN (see SmPC). Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC  $< 0.5 \times 10^9/l$  or platelet count  $< 50 \times 10^3/l$ . Do not initiate RoActemra treatment were ANC is below  $2 \times 10^9/l$ . Caution in patients with low platelet count; monitor neutrophils and platelets in RA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). Not recommended for use with other biological agents. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients – RoActemra not studied in patients during an active MAS episode. Trade name should be clearly recorded in patient file to improve traceability of biological medicines. **Drug Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or 2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions). **Fertility, Pregnancy & Lactation:** Women should use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-fetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. No lactation data in humans. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Refer to SmPC. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV:** RA: ADRs occurring in RoActemra trials: Very Common ( $> 1/10$ ): upper respiratory tract infections, 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: ADRs were similar to those seen in RA patients. Serious infections of varicella and otitis media reported (in addition to infections for RA). Hypersensitivity reactions requiring treatment discontinuation occurred in  $< 1\%$  of patients. Other events occurring within 24 hours of infusion (16% of patients) included rash, urticaria (considered serious), diarrhoea, epigastric discomfort, arthralgia and headache. Decreased IgG levels during therapy. pJIA: ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. 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. 20.2% experienced an infusion reaction within 24 hours of infusion. **RoActemra SC:** The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. See SmPC section 4.8 for instructions on the reporting of Suspected Adverse Reactions. **Legal Category:** Subject to medical prescription which may not be renewed (A). **Presentations & Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/001); 200mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** March 2015. **Reference:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. Int. J. Clin. Rheumatol. (2012) 7(1): 9-19. **Date of item:** February 2016. IE/RAC/TE/0216/0001



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