

SIMPONI® (golimumab)

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 01992 467272). By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION

A pre-filled pen and syringe each containing 50 mg of golimumab in 0.5 ml solution for injection.

A pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection.

USES

Rheumatoid Arthritis (RA): In combination with MTX to treat moderate to severe, active RA in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate and severe, active and progressive RA in adults not previously treated with MTX. Shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

Psoriatic Arthritis (PsA): To treat active and progressive PsA in adults when the response to DMARD therapy has been inadequate. 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.

Axial Spondyloarthritis:

Ankylosing Spondylitis (AS): To treat severe, active AS in adults who have responded inadequately to conventional therapy;

Non-Radiographic Axial Spondyloarthritis (nr-Axial SpA): To treat adults with severe, active nr-Axial SpA with objective signs of inflammation as indicated by elevated C-reactive protein and/or MRI evidence, who have had an inadequate response to, or are intolerant to NSAIDs.

Ulcerative colitis (UC): To treat 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 contraindications for such therapies.

DOSAGE AND ADMINISTRATION

Simponi should be injected subcutaneously (SC). Treatment should be initiated under the supervision of a physician experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial

SpA or UC. After training, patients may self-inject. **RA:** 50 mg given once a month, on the same date each month, concomitantly with MTX. **PsA, AS and nr-Axial SpA:** 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). Reconsider continued therapy in patients showing no evidence of therapeutic benefit within this time period.

RA, PsA, AS and nr-Axial SpA: *Patients weighing > 100 kg* who do not achieve an adequate clinical response after 3 or 4 doses, consider increasing the dose to 100 mg once a month, 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:* initial dose of 200 mg, followed by 100 mg at week 2. Patients who have an adequate response should receive 50 mg at week 6 and every 4 weeks. Patients with an inadequate response may benefit from continuing on 100 mg at week 6 and every 4 weeks thereafter. *Patients weighing ≥ 80 kg:* 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).

Older people (> 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

Hypersensitivity to golimumab or excipients; active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; moderate or severe heart failure (NYHA class III/IV).

PRECAUTIONS

Infections: Patients are more susceptible to serious infections: bacterial infections (including

sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. Monitor closely for infection before, during and for 5 months after treatment. Exercise caution in patients with chronic infection or a history of recurrent infection or on concomitant immunosuppressive therapy. Do not give to patients with clinically important active infection. Advise patients of the potential risk factors. Discontinue treatment if patient develops a new serious infection or sepsis and institute appropriate antimicrobial, antiviral or antifungal infection. Exclude active and latent TB before initiating treatment. Record all tests on the Patient Reminder Card. If latent TB is diagnosed, initiate anti-TB therapy before use of Simponi. Monitor all patients closely for signs and symptoms of active TB and advise patients to seek medical advice if signs and/or symptoms of TB appear. **Hepatitis B (HBV) reactivation:** Test for HBV infection before initiating treatment. Reactivation of HBV has occurred in chronic carriers, some with a fatal outcome. **Malignancies and lymphoproliferative disorders:** Exercise caution in patients who have history of malignancy and are at increased risk due to heavy smoking or develop a malignancy during therapy. 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 mostly in adolescent and young males on concomitant therapy with AZA or 6-MP. The potential risk with the combination of azathioprine (AZA) or 6-mercaptopurine (6-MP) and Simponi should be carefully considered. Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. Carefully assess the risks and benefits of continued treatment in newly diagnosed dysplasia patients. Melanoma and Merkel cell carcinoma have been reported; periodic skin examination is recommended, particularly for patients with risk factors for skin cancer.

Heart failure: Use with caution in patients with mild heart failure (NYHA class I/II). **Neurological events:** Consider discontinuing treatment in the event 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. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. **Surgery:** Closely monitor patients for infections if

surgery is required. **Autoimmune processes:** Discontinue treatment if symptoms suggestive of a lupus-like syndrome develop and antibodies against double-stranded DNA are present. **Haematologic reactions:** Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Consider discontinuing treatment in patients with significant haematologic abnormalities.

Vaccinations/therapeutic infectious agents: Concurrent administration of live vaccines or therapeutic infectious agents is not recommended. Paediatric patients should be brought up to date with all immunisations prior to initiation of treatment in agreement with current immunisation guidelines. **Allergic Reactions:** Discontinue immediately if an anaphylactic reaction or other serious allergic reaction occur and initiate suitable treatment. The needle cover of the pre-filled pen contains latex. **Renal and hepatic impairment:** Exercise caution with impaired hepatic function. **Special Populations:** Caution should be exercised when treating the elderly, particular attention should be paid to infections.

Simponi contains sorbitol (E420). Take into account in patients with rare hereditary problems of fructose intolerance.

Drug Interactions

Concomitant use with other biological therapeutics to treat the same conditions as Simponi, including anakinra and abatacept is not recommended.

Pregnancy and Lactation: 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 treatment.

SIDE-EFFECTS

Refer to Summary of Product Characteristic for complete information on side effects

Very Common ($\geq 1/10$): upper respiratory tract infection;

Common ($\geq 1/100$ to $< 1/10$): bacterial infections, lower respiratory tract infection, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, leukopenia (including neutropenia), anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus,

rash, alopecia, dermatitis, pyrexia, asthenia and injection site reaction, chest discomfort, bone fractures.

Serious, including fatal adverse events have been reported including septic shock, hepatitis B reactivation, tuberculosis, lymphoma, leukaemia, melanoma, Merkel cell carcinoma, Kaposi's sarcoma, hepatosplenic T-cell lymphoma*, thrombocytopenia, pancytopenia, aplastic anaemia, agranulocytosis, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome.

* Observed with other TNF-blocking agents.

PACKAGE QUANTITIES AND BASIC NHS COST

1 x 50 mg pre-filled pen or 1 x 50 mg pre-filled syringe: £762.97

1 x 100 mg pre-filled pen: £1525.94

MARKETING AUTHORISATION NUMBERS

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

Legal Category: POM

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