

ABBREVIATED PRESCRIBING INFORMATION

Enbrel® etanercept

Before prescribing Enbrel please refer to full Summary of Product Characteristics (SmPC).

Presentation: Enbrel Pre-filled Syringe: Enbrel 25 mg or 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC): Enbrel 25 mg or 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains either 25 mg or 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 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 nr-axSpA with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). **Children aged 2-17 years:** Juvenile idiopathic arthritis (JIA). Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis when inadequate response to, or intolerant of methotrexate. PsA 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:** PP 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: In order to improve the traceability of biological medicinal products, the brand name and batch number of the administered product should be clearly recorded (or stated) in the patient file. 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 Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure (CHF). There have been rare (< 0.1%) reports of new onset CHF, including CHF in patients without known pre-existing cardiovascular disease, including in patients under 50 years of age. Cases of active tuberculosis (TB) 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 immunisation 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. 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. Enbrel should only be used during pregnancy if clearly needed.

Undesirable Effects: Adults: The most commonly reported adverse reactions are injection site reactions, infections, headache, 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 bacterial sepsis. Various malignancies have also been reported with the 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, elevated liver enzymes, worsening of cardiac failure congestive, inflammatory bowel disease, rare reports of: TB, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, heart failure, autoimmune hepatitis, Steven Johnson's syndrome, anaphylaxis, interstitial lung disease and very rare reports of: toxic epidermal necrolysis, lichenoid reactions and aplastic anaemia have been reported. Kaposi's sarcoma, 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 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 a few cases of positive re-challenge. See section 4.8 of the SmPC for how to report adverse reactions.

Legal Category: POM.

Package Quantities: Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC): Each carton contains 4 pre-filled pens containing either 25 mg or 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.

Basic NHS Cost: 10 mg: £143.00 per carton; 25 mg (all presentations): £357.50 per carton; 50 mg (all presentations): £715 per carton.

European Marketing Authorisation Number:

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) 25 mg: EU/1/99/126/023

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

European Marketing Authorisation Holder: Pfizer Europe MA EElG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium.

GB Marketing Authorisation numbers

Enbrel 10 mg - Powder and solvent for solution for injection: PLGB 00057/1564

Enbrel 25 mg - Powder and solvent for solution for injection: PLGB 00057/1565

Enbrel 25 mg - Solution for injection pre-filled syringe and pre-filled pen (MYCLIC): PLGB 00057/1567

Enbrel 50 mg - Solution for injection pre-filled syringe and pre-filled pen (MYCLIC): PLGB 00057/1568

GB Marketing Authorisation Holder: Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

Further information is available on request from Medical Information Department at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK.

Date of Prescribing Information: March 2021

Doc ID: EN 21_0. Pfilet number: 2020-0059244 and 2019-0054967

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 Pfizer Medical Information on 01304 616161

