Prescribing information

Remsima® SC (infliximab)
Remsima® 120 mg solution for injection in pre-filled syringe and pre-filled pen. Prescribing information. United Kingdom. Please read the Summary of Product Characteristics (SPC) before prescribing.

Presentation
Each 1 mL single dose pre-filled syringe and in pre-filled pen contains 120 mg of infliximab for subcutaneous injection.

Indications
Rheumatoid Arthritis (RA): Remsima® in combination with methotrexate is indicated for the treatment 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) has been inadequately controlled in adult patients with severe, active and progressive RA not previously treated with MTX or other DMARDs.

Adult Crohn’s Disease (CD): Remsima® is indicated for the treatment of moderately to severely active CD in adult patients who have not responded to a full and adequate course of, are intolerant of, or have medical contraindications to therapy with a corticosteroid and/or an immunosuppressant; and fistulising active CD in adult patients who have responded to and tolerated a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).

Psoriatic Arthritis (PsA): Remsima® is indicated for the treatment of active and progressive PsA, in adult patients when the response to previous DMARD therapy has been inadequate.

Psoriasis (PsO): Remsima® is indicated for the treatment of moderate to severe plaque PsO in adult patients who have failed to respond to or, who have a contraindication to, or are intolerant of, conventional therapy including ciclosporin, MTX or PUVA.

Ulcerative Colitis (UC): Remsima® 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, who are intolerant of, or have medical contraindications for such therapies.

Ankylosing Spondylitis (AS): Remsima® is indicated for the treatment of the severe, active AS, in adult patients who have had an inadequate response to conventional therapy.

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Switching from intravenous to subcutaneous administration

Treatment with Remsima administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. A treatment with Remsima administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. If a patient does not respond by 6 weeks, no additional treatment with infliximab should be given. PsA: Treatment with Remsima administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. If a patient does not respond by 6 weeks, no additional treatment with infliximab should be given. PsO: Treatment with Remsima administered subcutaneously should be initiated as maintenance therapy 4 weeks after the last administration of two intravenous infusions of infliximab 5 mg/kg given 2 weeks apart. If a patient does not respond by 6 weeks, no additional treatment with infliximab should be given. Re-administration:

In case maintenance therapy is interrupted, and there is a need to restart treatment, use of a re-induction regimen of intravenous infliximab is not recommended (see section IV.8). In this situation, infliximab should be re-initiated as a single dose of intravenous infliximab followed by the maintenance dose recommendations of adalimumab in infliximab-desensitization failures. Patients may be pre-treated with e.g., an antihistamine, hydrocortisone and/or paracetamol to prevent mild and transient effects. Localised injection site reactions predominantly of mild to moderate in nature included erythema, pain, pruritus, swelling, induration, haemotoma, oedema, bruising, coldness, irritation, paraesthesia, ulcer, urtica, haemorrhage, rash and硬性. The majority of these reactions were resolved spontaneously without any treatment. Available data suggest an increased risk for delayed hypersensitivity with increasing infliximab free interval. Patients should be advised to seek immediate medical advice if they experience any delayed adverse reaction. If patients are re-treated after a prolonged period, they must be closely monitored for signs and symptoms of delayed hypersensitivity infections. Patients must be initiated on an immunosuppressant therapy before, during and up to 6 months after treatment with Remsima. Caution in patients with chronic infection or a history of recurrent infection. Patients should be advised of potential risk factors for infections. Suppression of TNFα has been associated with cases of new onset autoimmune processes; including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and risks of therapy must be considered before initiation. Discontinuation of Remsima should be considered if these disorders develop. Malignancies and lymphoproliferative disorders: A risk of the development of lymphomas and other malignancies in adolescents and young adults has occurred in patients with CD or UC treated concomitantly with AZA or 6-MP. Melanoma and Merkel cell carcinoma have been reported, particularly in patients with or at risk for developing a malignancy, in patients with PsO and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Possible increased risk of cervical cancer; periodic screening should continue in women treated with Remsima, including those over 60 years of age. Post-marketing cases of hepatocellular T-cell lymphoma have been reported in adult patients with severe disease who were treated with infliximab for rheumatoid arthritis or Crohn’s disease. 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 treatment with Remsima. Caution in patients with vigorous immune response, or who have a recent history of infections or have a history of infection with human herpes virus 8. Heart failure: Caution in patients with mild heart failure (NYHA class I/II) and discontinue in patients who develop new or worsening symptoms of heart failure (NYHA class III/IV). Other rare cancers related to infection with human herpes virus 8. Heart failure: Caution in patients with mild heart failure (NYHA class I/II) and discontinue in patients who develop new or worsening symptoms of heart failure (NYHA class III/IV).
May have a minor influence on the ability to drive and use machinery. **Interactions**

No interaction studies have been performed. Combination of Remsima with anakinra and abatacept as well as other biological therapeutics used to treat the same conditions as Remsima, is not recommended.

**Fertility, pregnancy and lactation**

Women of childbearing potential should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last Remsima treatment. Remsima should only be used during pregnancy if clearly needed. Administration of Remsima is not recommended when breast-feeding.

Cases of agranulocytosis in infants have been reported. Effects of infliximab on fertility and general reproductive function are unknown. Undesirable effects

Frequencies are defined at very common (≥1/10), common (≥1/1000 to <1/100), not known (cannot be estimated from the available data). Very common: viral infection (e.g. influenza, herpes virus infection), headache, upper respiratory tract infection, sinusitis, abdominal pain, nausea, pain. Common: bacterial infections (e.g. sepsis, cellulitis, abscess), neutropenia, leukaemia, anaemia, lymphopenopathy, allergic respiratory symptom, depression, insomnia, vertigo, dizziness, hypoaesthesia, paresthesia, conjunctivitis, tachycardia, palpitation, hypotension, hypertension, ecchymosis, hot flush, flushing, lower respiratory tract infection (e.g. bronchitis, pneumonia), dyspnea, epistaxis, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastrointestinal reflux, constipation, hepatic function abnormal, transaminases increased, new onset or worsening psoriasis including pustular psoriasis (primarily palm and soles), urticarial, rash, pruritis, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, althralgia, myalgia, back pain, urinary tract infection, chest pain, fatigue, fever, injection site reaction, chills, oedema.

Not known: vaccine breakthrough infection (after in utero exposure to infliximab, hepatosplenic T-cell lymphoma (primarily in adolescents and young adult males with Crohn’s disease and ulcerative colitis), Merkel cell carcinoma, transient visual loss occurring during or within 2 hours of infusion, myocardial infarction, liver failure, worsening of symptoms of dermatomyositis, Kaposi’s sarcoma. Serious, including fatal, adverse reactions have been reported, including HBV reactivation, CHF (congestive heart failure), serious infections (including sepsis, opportunistic infections and TB), serum sickness (delayed hypersensitivity reactions), haematologic reactions, systemic lupus erythematosus/lupus-like syndrome, demyelinating disorders, hepatobiliary events, lymphoma, HSTCL, leukaemia, Merkel cell carcinoma, melanoma, sarcoidosis/sarcoid-like reaction, and serious infusion reactions. Other less common and rarely reported adverse reactions are listed in the SmPC. Prescribers should consult the Summary of Product Characteristics for full prescribing information.

Special precautions for storage

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the medicinal product in its outer carton in order to protect from light. The medicinal product may be stored at temperatures up to a maximum of 25°C for a period of up to 28 days. The medicinal product must be discarded if not used within the 28-day period.

**Legal category** POM

**Presentations and basic NHS costs:** Remsima SC (infliximab) 120 mg solution for injection in pre-filled pen (pack size 2 is £755.32, £377.66 per unit); Remsima SC (infliximab) 120 mg solution for injection in pre-filled syringe (pack size 2 is £755.32, £377.66 per unit)

**Marketing Authorisation numbers** EU/1/13/853/001

**Marketing Authorisation holder**

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Celltrion Healthcare and its authorised commercialisation partners by calling +44 (0)1279 406759 (Diamond Pharma Services)

**Date of Pi Preparation** Oct 2020 CTHC-UK-201(1)