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 (MTX) or with or without prednisolone 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 inadequate 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 not responded to 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, including psoriatic arthritis, in adult patients when the response to previous DMARD therapy has been inadequate in adult patients with PsA who are intolerant of, or have medical contraindications to other conventional therapies.

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 intolerance of, conventional therapy including ciclosporin, MTX or PUVA.

Dosage and administration Remsima® should be administered subcutaneously. The recommended dosage and administration is 120 mg every 2 weeks for adult patients with active RA who have not previously been treated with infliximab, and for active CD and PsA. Remsima® is recommended for induction therapy in at least 10% of adult patients who have previously been treated with infliximab. As a general rule, treatment should be continued for at least 1 year but may be continued longer if the response is maintained. Remsima® should be used cautiously in patients who have a medical history of demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and potential risks of treatment should be carefully considered before initiation. Discontinuation of Remsima® should be considered if these disorders develop.

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 (MTX) or with or without prednisolone 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 inadequate 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 not responded to 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, including psoriatic arthritis, in adult patients when the response to previous DMARD therapy has been inadequate in adult patients with PsA who are intolerant of, or have medical contraindications to other conventional therapies.

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 intolerance of, conventional therapy including ciclosporin, MTX or PUVA.

Dosage and administration Remsima® should be administered subcutaneously. The recommended dosage and administration is 120 mg every 2 weeks for adult patients with active RA who have not previously been treated with infliximab, and for active CD and PsA. Remsima® is recommended for induction therapy in at least 10% of adult patients who have previously been treated with infliximab. As a general rule, treatment should be continued for at least 1 year but may be continued longer if the response is maintained. Remsima® should be used cautiously in patients who have a medical history of demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and potential risks of treatment should be carefully 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, including sarcomas, in patients treated with infliximab and other TNF-inhibitors including etanercept and adalimumab has been observed. The risk is estimated to be increased in patients with a history of demyelinating disorders, such as Guillain-Barré syndrome or multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and potential risks of treatment should be carefully considered before initiation. Discontinuation of Remsima® should be considered if these disorders develop.
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, lekopenia, anaemia, lymphadenopathy, 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, dyspnea, 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, atophagia, 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 ischaemia/myocardial infarction, liver failure, worsening of symptoms of dermatomyositis, 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/sarcoïd-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
Celltrion Healthcare Hungary Kft 1062 Budapest
Váci út 1-3, WestEnd Office Building B Torony. Hungary

For medical information enquiries, please contact UKmedical@celltrionhc.com

® Remsima is a registered trade mark of Celltrion, Inc. and is used under licence.

© 2020 Celltrion Healthcare Ltd.