DOSING GUIDE

Remsima® Infliximab
SUBCUTANEOUS

Remsima® subcutaneous formulation is available as pre-filled pen and pre-filled syringe.

Remsima® 120 mg solution for injection in pre-filled pen

Remsima® 120 mg solution for injection in pre-filled syringe with needle guard

Indications and posology[1]

Remsima® subcutaneous formulation is indicated for **adult** patients with the following conditions.

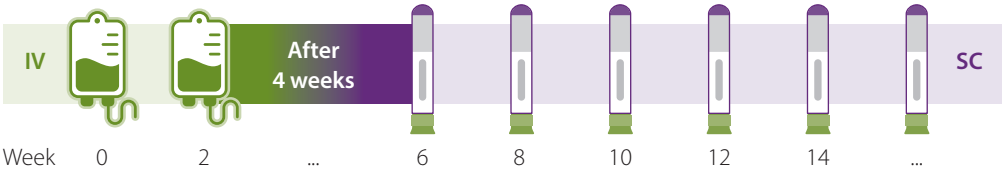
Indication	Posology
Moderate to severe **Plaque Psoriasis**	• **IV induction with infliximab 5 mg/kg** at Week 0, 2 • **SC maintenance with Remsima® 120 mg dose every 2 weeks**, starting from Week 6

*For subcutaneous injection, 120mg is fixed dose for all adult patients, independent of weight.

Dosing schedules[1]

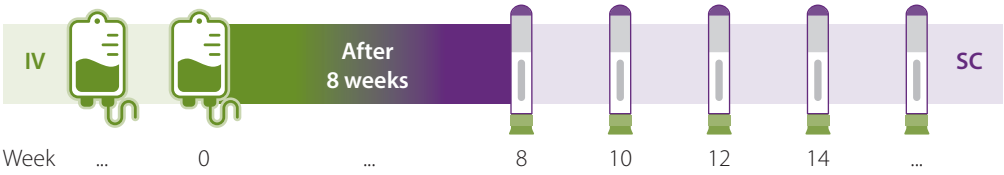
Remsima® SC initiation

- 4 weeks after the last administration of two infliximab intravenous infusions given at week 0 and 2.
- Continue with fortnightly administration of Remsima® subcutaneous formulation starting from week 6.



Switching from the maintenance therapy of infliximab intravenous

- Commence Remsima® subcutaneous formulation 8 weeks after the last administration of the infliximab intravenous (IV)
- Continue with fortnightly administration of Remsima® subcutaneous formulation



Special populations[1]

- No major age-related differences in clearance or volume of distribution were observed in clinical studies with infliximab intravenous formulations and the same is expected for subcutaneous formulation.
- No dose adjustment is required in elderly patients (65+).

- Safety and efficacy not established for children and adolescents under age 18. Therefore, subcutaneous use of Remsima® is recommended for use only in adults.

Important dosing information[1]

Missed Dose

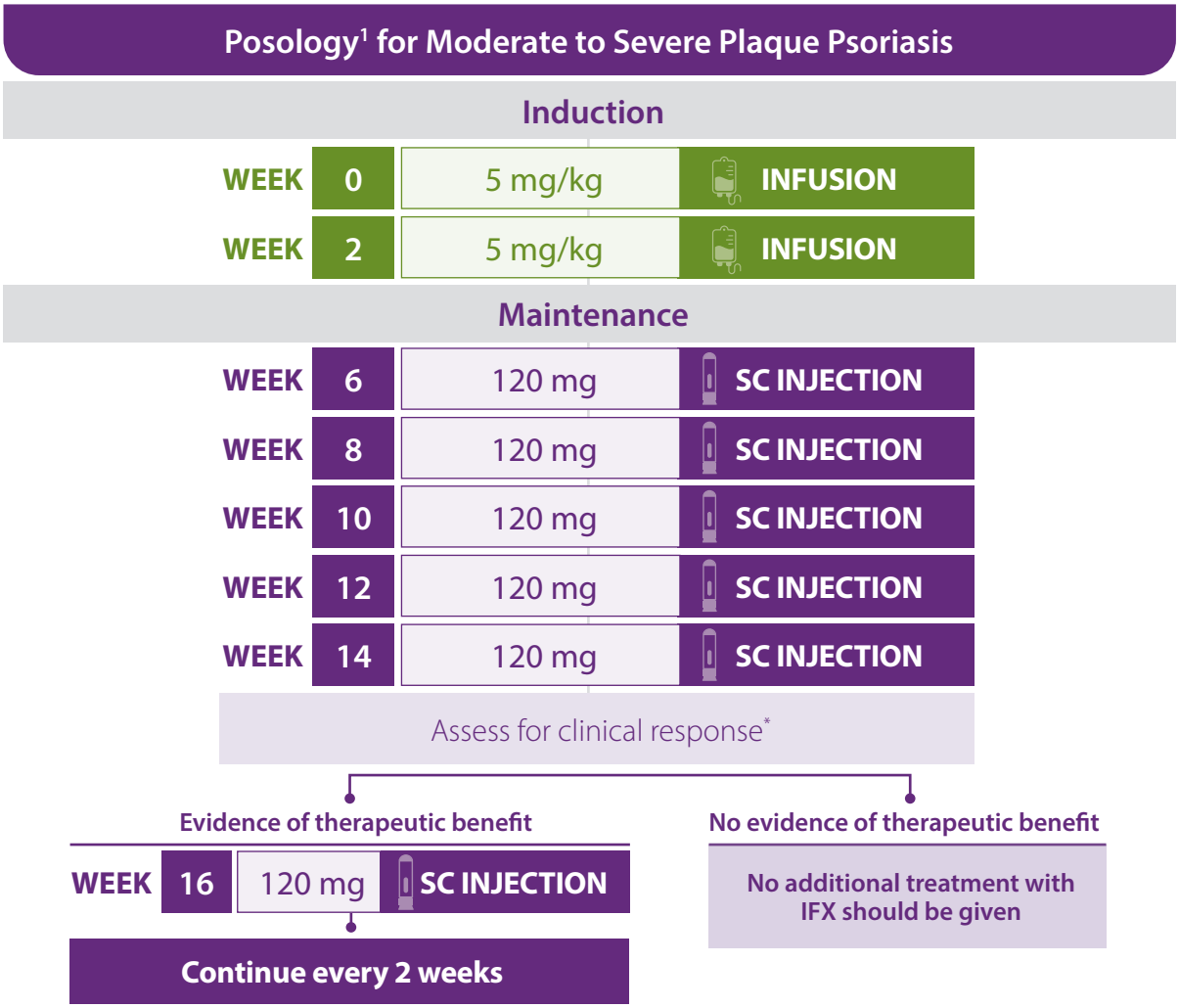
Missed dose within 7 days
If patients miss an injection of Remsima® subcutaneous formulation, they should be instructed to take the missed dose immediately if they remember within 7 days of the missed dose, and then continue on their original fortnightly dosing schedule.[1]

Missed dose for 8 days or more
If the dose is **delayed by 8 days or more,** the patients should be instructed to **skip the missed dose, wait until their next scheduled dose,** and then remain on their original fortnightly dosing schedule.[1]

Readmistration

Re-administration across indications
If maintenance therapy is interrupted, infliximab should be re-initiated as a single dose of intravenous infliximab followed by the maintenance dose recommendations of subcutaneous infliximab described above given 4 weeks after the last administration of intravenous infliximab.[1]

Posology[1] for Moderate to Severe Plaque Psoriasis



*If a patient shows no response after 14 weeks (i.e. 2 intravenous infusions and 5 subcutaneous injections), no additional treatment with infliximab should be given.

Re-administration for Plaque Psoriasis

Limited experience from re-treatment with one single intravenous infliximab dose in psoriasis 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.

PBS Information: Authority required for the treatment of severe chronic plaque psoriasis. Refer to PBS Schedule for full authority information.

Before prescribing, please review full product information available on request from the Celltrion Healthcare Medical Information Service (Phone: 1800 325 228) or via www.ebs.tga.gov.au.

MINIMUM PRODUCT INFORMATION REMSIMA® SC REMSIMA® SC containing 120 mg infliximab (IFX) for subcutaneous (SC) injection in a 1-mL single dose pre-filled pen or syringe. **INDICATIONS**: adult patients with moderate to severe plaque PsO for whom phototherapy or conventional systemic treatments were inadequate or are inappropriate. **CONTRAINDICATIONS**: Severe infections (e.g. sepsis, abscesses, tuberculosis and opportunistic infections); history of hypersensitivity to IFX, other murine proteins or any excipient; concurrent administration with anakinra; congestive heart failure or moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS**: Systemic injection reactions, anaphylactic shock and delayed hypersensitivity reactions have been reported. Localised injection site reactions have been reported following SC administration; Malignancies and lymphoproliferative disorders, risk of development of lymphomas/other malignancies cannot be excluded. Caution with history of malignancy, with increased risk for malignancy, and treating patients who develop a malignancy; Skin Cancers, patients should be monitored for non-melanoma skin cancers, particularly those who have had prior prolonged phototherapy treatment; Infections, monitor closely for infections including TB before, during and up to 6 months after treatment. Caution with chronic infection or a history of recurrent infection. Suppression of TNF may mask symptoms of infection such as fever; Hepatitis B (HBV) reactivation, reactivation of HBV has occurred in chronic carriers when receiving IFX. Test for HBV infection before initiating treatment and closely monitor for symptoms of active HBV; Hepatobiliary events, 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/therapeutic infectious agents: prior to therapy vaccinations should be up to date. Live vaccines or therapeutic infectious agents not recommended. Min. 6-month waiting period after birth before use of live vaccines to infants exposed in utero to IFX; Autoimmune processes, discontinue treatment if symptoms suggestive of a lupus-like syndrome and positive for antibodies against double-stranded DNA; Neurological events, anti-TNF agents are associated with new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis; Heart failure, caution with mild heart failure (NYHA class I/II) and discontinue when new or worsening symptoms of heart failure develop; Haematologic reactions, consider discontinuation when significant haematologic abnormalities, including pancytopenia, leukopenia, neutropenia and thrombocytopenia; Use in the elderly, caution in the treatment of elderly patients (greater frequency of decreased hepatic, renal and/or cardiac function and concomitant disease and/or other drug therapy); Fertility, pregnancy and lactation, women of childbearing potential should consider adequate contraception to prevent pregnancy and continue use for ≥ 6 months after treatment. Not recommended for use during pregnancy and lactation. Breastfeeding should be discontinued for ≥ 6 months after treatment; Paediatric use, safety and efficacy of IFX SC therapy in children < 18 years is not established. **INTERACTIONS**: No specific drug interaction studies conducted. Combination with anakinra is contraindicated, use with abatacept as well as other biological therapeutics used to treat the same conditions not recommended. IFX should not be used in combination with immunosuppressive agents or phototherapy due to the possibility of excessive immunosuppression. Caution in patients with medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. **ADVERSE EFFECTS** (AEs): Very common, localised injection site reactions; Common, viral infection, fever, serum-sickness-like reactions, headache, vertigo/dizziness, flushing, upper respiratory tract infection, lower respiratory tract infection, dyspnoea, sinusitis, nausea, diarrhoea, abdominal pain, dyspepsia, abnormal hepatic function, rash, pruritus, urticaria, increased sweating, dry skin, fatigue, chest pain, infusion-related reactions. The safety profile of REMSIMA® SC in clinical trials was overall similar to the safety profile of the IV formulation. For other less common and rarely reported AEs see full PI. **DOSAGE AND ADMINISTRATION**: treatment with Remsima® SC should be initiated as maintenance therapy 4 weeks after the last administration of two IV infusions of IFX 5 mg/kg given 2 weeks apart. The recommended dose for Remsima® SC is 120 mg once every 2 weeks.

References: 1. Remsima(r) Australian Approved Product Information available at https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-02558-1&d=20230219172310101. Last accessed: 20.02.2023.

IFX, Infliximab; IV, intravenous; kg, kilograms mg; milligrams; MTX, methotrexate; SC, subcutaneous

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