Tremfya100 mg solution for injection in pre-filled pen
PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Guselkumab

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Treatment of active psoriatic arthritis in adult patients, alone or in combination with methotrexate, who have had an inadequate response or have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

DOSAGE & ADMINISTRATION: For use under guidance/supervision of physician experienced in diagnosis and treatment of conditions for which Tremfya is indicated. Subcutaneous injection. Avoid areas showing psoriasis. **Adults:** For both indications,100 mg at weeks 0 and 4, followed by maintenance dose every 8 weeks. In the case of psoriatic arthritis, for patients at high risk for joint damage according to clinical judgement, consider a dose of 100 mg every 4 weeks. Consider discontinuation if no response after 16 weeks of treatment for plaque psoriasis and 24 weeks for psoriatic arthritis. **Children:** No data available in children/adolescents <18 years. **Elderly:** No dose adjustment required, limited information in subjects aged ≥ 65 years, very limited information > 75 years. **Renal & Hepatic impairment:** Not studied.

CONTRAINDICATIONS: Serious hypersensitivity to active substance or excipients; clinically important, active infection.

SPECIAL WARNINGS & PRECAUTIONS: ***Infections:*** Potential to increase risk. If signs/symptoms of clinically important chronic/acute infection occur, monitor closely and discontinue Tremfya until resolved. ***Tuberculosis:*** Evaluate patients for TB pre-treatment; monitor for signs/symptoms of active TB during and after treatment. Consider anti-TB therapy prior to Tremfya if past history of latent/active TB and adequate treatment course not confirmed. ***Serious hypersensitivity reaction:*** Includes anaphylaxis. Some serious hypersensitivity reactions occurred several days after treatment and included urticaria and dyspnoea. If occurs, discontinue Tremfya immediately and initiate appropriate therapy. ***Hepatic Transaminase Elevations:*** An increased incidence of liver enzyme elevations has been observed in patients treated with Tremfya q4w compared to patients treated with Tremfya q8w or placebo. When prescribing Tremfya q4w in psoriatic arthritis, consider evaluating liver enzymes at baseline and thereafter according to routine patient management. If increases in ALT or AST are observed and drug-induced liver injury is suspected, Tremfya should be temporarily interrupted until this diagnosis is excluded. ***Immunisations:*** Consider completing all appropriate immunisations prior to Tremfya. Do not use live vaccines concurrently with Tremfya; no data available; before live vaccination, withhold Tremfya for at least 12 weeks and resume at least 2 weeks after vaccination.

SIDE EFFECTS: Very common: Respiratory tract infection. **Common:** headache, diarrhoea, arthralgia, injection site reactions, transaminases increased. **Other side effects:** hypersensitivity, anaphylaxis, rash, herpes simplex infections, neutrophil count decreased.
Refer to SmPC for other side effects.

LEGAL CATEGORY: Prescription Only Medicine (POM)

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S)

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)
Pre-filled pen	X 1	EU/1/17/1234/002

MARKETING AUTHORISATION HOLDER:
Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, IRL - Co. Cork, P43 FA46.
Prescribing information last revised: July 2022

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via:
HPRA Pharmacovigilance
Website: www.hpra.ie

Adverse events should also be reported to Janssen Sciences Ireland UC on 1800 709 122 or at dsafety@its.jnj.com.