Tremfya 100 mg solution for injection in pre-filled pen (PFP), 200 mg solution for injection in pre-filled pen (PFP) and 200 mg concentrate for solution for infusion (SFI)

ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Guselkumab

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

INDICATION(S): 100 mg PFP: 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. 100 mg PFP, 200 mg PFP and 200 mg SFI: Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biologic treatment. Treatment of adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment.

DOSAGE & ADMINISTRATION: For use under guidance/supervision of physician experienced in diagnosis and treatment of conditions for which Tremfya is indicated. **Adults:** For both plaque psoriasis and psoriatic arthritis 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. For UC, induction dose is 200mg administered by IV infusion at weeks 0, 4 and 8, followed by a maintenance dose starting at Week 16 of 100mg SC every 8 weeks. For CD, either of the following two induction dose regimens are recommended; 1) 200mg administered by IV infusion at weeks 0, 4 and 8 or 2) 400 mg (2 x 200mg injections) administered by SC injection at Weeks 0, 4 and 8. The subsequent maintenance dose starting at Week 16 is 100 mg by SC injection every 8 weeks. For both UC and CD patients not showing adequate therapeutic benefit to induction treatment according to clinical judgement, alternatively a maintenance dose regimen of 200 mg administered by SC injection starting at Week 12 and every 4 weeks thereafter, may be considered. Immunomodulators and/or corticosteroids may be continued during treatment with guselkumab. In patients who have responded to treatment with guselkumab, corticosteroids may be reduced or discontinued in accordance with standard of care. Consider discontinuation if no response after 16 weeks of treatment for plaque psoriasis or after 24 weeks for psoriatic arthritis, ulcerative colitis and Crohn's disease. **Missed dose:** Administer missed dose as soon as possible and thereafter resume dosing at regular scheduled time. **Children:** No data available in children/adolescents <18 years. **Elderly:** No dose adjustment required, limited information in patients aged ≥ 65 years, very limited information in patients aged > 75 years. **Renal or Hepatic impairment:** Not studied in patient populations, based on pharmacokinetics of monoclonal antibodies, no dose adjustments are considered necessary. **Method of Administration**: 100 mg and 200 mg PFP are for SC use only. Sites for injection include the abdomen, thigh and back of the upper arm. Do not inject into areas where skin is tender, bruised, red, hard, thick or scaly. 200 mg SFI is for IV use only. It should be administered over a period of at least one hour.

CONTRAINDICATIONS: Serious hypersensitivity to active substance or excipients; clinically important, active infection (e.g. active tuberculosis).

SPECIAL WARNINGS & PRECAUTIONS: Please refer to SmPC for information on the following special warnings and precautions: Traceability, Infections**,** Pre-treatment evaluation for tuberculosis, Hypersensitivity, Hepatic transaminase elevations, Immunisations, Excipients with known effect.

SIDE EFFECTS: Very common: Respiratory tract infection. **Common:** headache, diarrhoea, rash, arthralgia, transaminases increased. **Uncommon:** herpes simplex infections**,** tinea infections, gastroenteritis, urticaria, injection site reactions, neutrophil count decreased.
Refer to SmPC for further information on side effects.

LEGAL CATEGORY: Prescription Only Medicine (POM)

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S)

PRESENTATIONS	**PACK SIZES**	**MARKETING AUTHORISATION NUMBER(S)**
100 mg solution for injection in pre-filled pen	X 1	EU/1/17/1234/002
200 mg solution for injection pre-filled pen	X 1	EU/1/17/1234/008
200 mg concentrate for solution for infusion	X 1	EU/1/17/1234/005

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 updated: May 2025

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC, a Johnson & Johnson company, on 0044 1494 567447 or at dsafety@its.jnj.com.