Tremfya 100 mg solution for injection in pre-filled pen
Tremfya 200 mg concentrate for solution for infusion
Tremfya 200 mg PushPen 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. Treatment of adult patients with moderately to severely active Crohn's disease 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 ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor.

DOSAGE & ADMINISTRATION: For use under guidance/supervision of physician experienced in diagnosis and treatment of conditions for which Tremfya is indicated. Please refer to the Instructions for Use (IFU) for injection areas. **Adults:** For 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. Consider discontinuation if no response after 16 weeks of treatment for plaque psoriasis and after 24 weeks for psoriatic arthritis. For Crohn's disease (CD): The recommended induction dose is: 200 mg administered by intravenous infusion at Week 0, Week 4, and Week 8 or 400 mg administered by subcutaneous injection (given as two consecutive injections of 200 mg each) at Week 0, Week 4 and Week 8. See SmPC for Tremfya 200 mg concentrate for solution for infusion. After completion of the induction dose regimen, the recommended maintenance dose starting at Week 16 is 100 mg administered by subcutaneous injection every 8 weeks (q8w). Alternatively, for patients who do not show adequate therapeutic benefit to induction treatment according to clinical judgement, a maintenance dose of 200 mg administered by subcutaneous injection starting at Week 12 and every 4 weeks (q4w) thereafter, may be considered. For Ulcerative Colitis (UC): The recommended induction dose is 200 mg administered by intravenous infusion at week 0, week 4 and week 8 or 400 mg administered by subcutaneous injection (given as two consecutive injections of 200 mg each) at Week 0, Week 4 and Week 8. See SmPC for Tremfya 200 mg concentrate for solution for infusion. After completion of the induction dose regimen, the recommended maintenance dose starting at Week 16 is 100 mg administered by subcutaneous injection every 8 weeks (q8w). Alternatively, for patients who do not show adequate therapeutic benefit to induction treatment according to clinical judgment, a maintenance dose of 200 mg administered by subcutaneous injection starting at Week 12 and every 4 weeks (q4w) thereafter, may be considered. UC/CD: 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.
Consideration should be given to discontinuing treatment in patients who have shown no evidence of therapeutic benefit after 24 weeks of treatment.

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.
Refer to SmPC for full list of excipients.

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 a serious hypersensitivity reaction 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, rash arthralgia, transaminases increased. **Other side effects:** hypersensitivity, anaphylaxis, gastroenteritis, herpes simplex infections, tinea infections, injection site reactions, neutrophil count decreased, urticaria.
Refer to SmPC for more detail on side effects.

PREGNANCY: Avoid use of Tremfya; limited data. As a precautionary measure, it is preferable to avoid the use of Tremfya during pregnancy. Women of childbearing potential should use effective contraception during and for at least 12 weeks after treatment.

LACTATION: It is unknown whether guselkumab is excreted in human milk. A decision should be made to discontinue or abstain from initiating treatment with Tremfya taking into account the benefit of breast-feeding to the child and the benefit of Tremfya therapy to the woman. Refer to SmPC for more information.

INTERACTIONS: No dose adjustment when co-administering with CYP450 substrates. Concomitant immunosuppressive therapy or phototherapy not evaluated.
Refer to SmPC for full details of interactions.

LEGAL CATEGORY: Prescription Only Medicine (POM)

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S) & BASIC NHS COSTS

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)	BASIC NHS COSTS
Pre-filled pen (100 mg)	X 1	PLGB 00242/0665	£2250
PushPen solution for injection in pre-filled pen (200 mg)	X 1	PL 00242/0766	£2250
PushPen solution for injection in pre-filled pen (200 mg)	X 2	PL 00242/0766	£4500
200mg concentrate for solution for infusion	X 1	PL 00242/0767	£4500

MARKETING AUTHORISATION HOLDER:
United Kingdom: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK
FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Prescribing information last revised: August 2025

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.