STELARA® 45 mg and 90 mg solution for injection in pre-filled syringe
STELARA ® 45 mg and 90 mg solution for injection in pre-filled pen
STELARA® 45 mg solution for injection
STELARA ® 130 mg concentrate for solution for infusion
ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Ustekinumab

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

INDICATION(S): Plaque psoriasis adults: Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA.
Plaque psoriasis paediatrics: Moderate to severe plaque psoriasis in children and adolescent patients from 6 years of age, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
Psoriatic arthritis: Alone or in combination with methotrexate for treatment of active psoriatic arthritis in adult patients when response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.
Adult Crohn's disease: Treatment of adult patients with moderately to severely active Crohn's disease who had inadequate response with/lost response to/were intolerant to either conventional therapy or TNFα antagonist.
Paediatric Crohn' s Disesase: Treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy.
Ulcerative colitis: Treatment of adult patients with moderately to severely active ulcerative colitis who had an inadequate response with/lost response to/were intolerant to either conventional therapy or a biologic.

DOSAGE & ADMINISTRATION: ***Adults:*** Under guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis/psoriatic arthritis/Crohn's disease/ulcerative colitis. **Psoriasis or psoriatic arthritis**. Subcutaneous (s.c.) injection. Avoid areas with psoriasis. Self-injecting patients or caregivers ensure appropriate training. Physicians are required to follow-up and monitor patients.
Plaque psoriasis, adults & elderly: Patients up to and including 100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients greater than 100 kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients).
Plaque psoriasis paediatrics (6 years and older): Patients under 60 kg, 0.75 mg/kg at week 0, followed by 0.75 mg/kg at week 4 then every 12 weeks thereafter. Patients 60 - 100kg, 45 mg at week 0 followed by 45 mg at week 4, then every 12 weeks. Patients greater than 100 kg, 90mg at week 0, followed by 90mg at week 4, then every 12 weeks. The pre-filled pen has not been studied in the paediatric population and is not recommended for use in paediatric patients.
Psoriatic arthritis, adults & elderly: 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg. Consider discontinuation if no response after 28 weeks.
Crohn's disease and ulcerative colitis, adults & elderly: Initial single intravenous infusion dose based on body weight (260 mg or 390 mg or 520 mg) diluted in sodium chloride solution and given over at least one hour. At week 8 after intravenous dose, 90 mg s.c. dose is given; followed by every 12 weeks (or 8 weeks based on clinical judgement). Consider discontinuation if no response 16 weeks after the IV induction dose or 16 weeks after switching to the 8-weekly maintenance dose. Immunomodulators and/or corticosteroids may be continued but consider reducing/discontinuing

corticosteroids if responding to Stelara. In Crohn's disease, if therapy interrupted, resume s.c. every 8 weeks if safe/effective.
Crohn's disease paediatrics (patients weighing at least 40 kg): Initial single intravenous infusion dose based on body weight (260 mg or 390 mg or 520 mg) diluted in sodium chloride solution and given over at least one hour. At week 8 after intravenous dose, 90 mg s.c. dose is given; followed by every 12 weeks (or 8 weeks based on clinical judgement). Consider discontinuation if no evidence of therapeutic benefit 16 weeks after the IV induction dose or 16 weeks after switching to the 8-weekly maintenance dose. Immunomodulators, 5-aminosalicylate (5-ASA) compounds, antibiotics and/or corticosteroids may be continued but consider reducing/discontinuing these medications if responding to Stelara. The pre-filled pen has not been studied in the paediatric population and is not recommended for use in paediatric patients.
Children: **under 6 years -** Not recommended for psoriasis. **under 18 years** - Not recommended for psoriatic arthritis and ulcerative colitis. **Paediatric patients weighing less than 40 kg** – not recommended for Crohn' s disease. ***Renal & Hepatic impairment:*** Not studied.

CONTRAINDICATIONS: Hypersensitivity to product; clinically important, active infection.

SPECIAL WARNINGS & PRECAUTIONS: Please refer to SmPC for information on the following special warnings and precautions: Traceability, Infections, Malignancies, Systemic hypersensitivity reactions, Infusion-related reactions, Respiratory hypersensitivity reactions, Cardiovascular events, Latex-sensitivity, Vaccinations, Concomitant immunosuppressive therapy, Immunotherapy, Serious skin conditions, Lupus-related conditions, Special populations, Sodium content, Polysorbate 80.

SIDE EFFECTS: ***Common:*** upper respiratory tract infection, nasopharyngitis, sinusitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, vomiting, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain. ***Uncommon:*** cellulitis, dental infections, herpes zoster, lower respiratory tract infection, viral upper respiratory tract infection, vulvovaginal mycotic infection, hypersensitivity reactions (including rash, urticaria), depression, facial palsy, nasal congestion, pustular psoriasis, skin exfoliation, acne, injection site reactions (including haemorrhage, haematoma, induration, swelling and pruritus), asthenia.

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)
45 mg	1 x vial	EU/1/08/494/001
45 mg	1 x 0.5 ml pre-filled syringe	EU/1/08/494/003
90 mg	1 x 1.0 ml pre-filled syringe	EU/1/08/494/004
130 mg	1 x vial	EU/1/08/494/005
45mg	1 x 0.5ml pre-filled pen	EU/1/08/494/006
90mg	1 x 1ml pre-filled pen	EU/1/08/494/007

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: April 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 on 0044 1494 567447 or at dsafety@its.jnj.com.