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
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.
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 or have contraindications to such therapies.
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 or have contraindications to such therapies.

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 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.

Children: under 6 years - Not recommended for psoriasis. **under 18 years** - Not recommended for psoriatic arthritis, Crohn's disease and ulcerative colitis. ***Renal & Hepatic impairment:*** Not studied.

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

SPECIAL WARNINGS & PRECAUTIONS: ***Infections:*** Potential to increase risk of infections and reactivate latent infections. Opportunistic infections have been reported in patients treated with ustekinumab. Caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis prior to initiation of STELARA. Consider anti-tuberculosis therapy prior to initiation of STELARA in patients with history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, closely monitor and STELARA should not be administered until infection resolves. ***Malignancies****:* Potential to increase risk of malignancy. Risk of malignancy may be higher in psoriasis patients treated with other biologics. No studies in patients with history of malignancy or in patients who develop malignancy while receiving STELARA. Monitor all patients, in particular those older than 60, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment for non-melanoma skin cancer. ***Cardiovascular events:*** Cardiovascular events have been observed in patients with psoriasis in a post marketing observational study; cardiovascular risk factors should be regularly assessed during treatment. ***Concomitant immunosuppressive therapy:*** Caution, including when changing immunosuppressive biologic agents. ***Hypersensitivity reactions:*** Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur appropriate therapy should be instituted and STELARA discontinued. ***Latex sensitivity:*** Needle cover contains natural rubber (latex), may cause allergic reactions. ***Immunotherapy:*** Not known whether STELARA affects allergy immunotherapy. ***Serious skin conditions:*** Exfoliative dermatitis reported following treatment. Discontinue STELARA if drug reaction is suspected. **Infusion-related** anaphylactic reactions to the infusion have been reported. If a serious or life-threatening reaction is observed, appropriate therapy should be instituted and ustekinumab should be discontinued. ***Vaccines:*** Administration of live vaccines to infants is not recommended for six months following birth. ***Lupus-related conditions:*** Cases of lupus-related conditions have been reported in patients treated with ustekinumab.

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.
Other side effects: cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema), skin exfoliation, exfoliative dermatitis, lower respiratory tract infection.
Very rare: bullous pemphigoid, cutaneous lupus erythematosus, lupus-like syndrome
Studies show adverse events reported in children 12 years and over with plaque psoriasis were similar to those seen in previous studies in adults with plaque psoriasis.

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)**
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:June 2023.

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.