General Information about Stelara®

Stelara® (ustekinumab)

It is important you read the prescribing information (PI) on the reverse for further information.
For full prescribing information refer to the Summary of Product Characteristics.

- **Stelara® (ustekinumab) is a biologic medicine which blocks interleukin IL-12 and IL-23. Stelara has two indications.**
- **It is indicated for the 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 (MTX) and PUVA.**
- **Moderate to severe plaque psoriasis in adolescents (aged 12 years or older) who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.**
- **It is also indicated for treatment of active psoriatic arthritis in adult patients, alone or in combination with MTX, when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.[1]**

Stelara® efficacy & safety

- Stelara® has demonstrated in clinical trials that it can provide patients with significant improvements in their psoriasis and psoriatic arthritis, as measured by PASI and ACR scores.[1]
- Psoriasis patients receiving Stelara® showed significant improvement in skin symptoms (PASI 75 response) 12 weeks after initiating therapy.[1,2,3] Maintenance of PASI 75 response has been demonstrated in long term follow-up of up to 5 years in patients following the every-12-week dosing schedule.[4]
- Treatment for psoriatic arthritis with Stelara® resulted in significant improvements in the ACR20 score compared to placebo at Week 24. Efficacy was maintained through one year of continuous treatment with Stelara®. In addition, Stelara®-treated patients showed significant improvement in physical function asassessed by the Disability Index of the Health Assessment Questionnaire (HAQ-DI) at Week 24. The proportion of patients achieving a clinically meaningful ≥ 0.3 improvement in HAQ-DI score from baseline was also significantly greater in the Stelara® groups when compared with placebo. Improvements in physical function were maintained at Week 52.[5]
- Adverse events seen in trials of Stelara® include: diarrhoea, nausea, fatigue, dizziness, pruritus, back pain, headache, myalgia, arthralgia, oropharyngeal pain, dental infections, upper respiratory tract infections, nasopharyngitis, injection site erythema and injection site pain, antibodies to ustekinumab.[1]
- The Stelara® psoriasis clinical trial safety database contains over 3,000 patients treated to date, some for up to 5 years.[6]
- The safety of ustekinumab has been studied in a phase 3 study of 110 patients from 12 to 17 years of age for up to 60 weeks. In this study, the adverse events reported were similar to those seen in previous studies in adults with plaque psoriasis.

The role of an IL-12 and IL-23 inhibitor

- The cytokines IL-12 and IL-23 have a central role in the development and maintenance of the inflammatory cascade in psoriatic diseases and have been shown to be important targets for therapeutic interventions.[7,8]
- Stelara® is a fully human monoclonal antibody which inhibits the activity of the cytokines IL-12 and IL-23.[9]
- Rates of adverse events recorded in the paediatric study were similar to those recorded in the adult psoriasis population treated with Stelara®.[1]

Stelara® dosing, storage and handling[1]

- Stelara® is administered by a subcutaneous injection.
- For psoriasis, the recommended posology of Stelara® is an initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter. For patients with a body weight >100 kg the initial dose is 90 mg administered subcutaneously, followed by a 90 mg dose 4 weeks later, and then every 12 weeks thereafter.
- For psoriasis in adolescents (aged 12 years or older), the recommended dose is 0.75mg/kg for patients < 60kg, 45mg for patients ≥ 60kg–≤ 100kg, and 90mg for patients > 100kg.
- For psoriatic arthritis the recommended posology of Stelara® is an initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight > 100 kg.
- Stelara® should be administered at weeks 0 and 4, then every 12 weeks thereafter.
- Stelara® comes in a pre-filled syringe or vial and should be stored in a refrigerator between 2°C and 8°C and not frozen. It should be kept in its original outer packaging to protect it from light and it should not be shaken. It should be allowed to reach room temperature (approximately half an hour out of the fridge) before administration.
- Stelara® solution is clear to slightly opalescent, colourless to light yellow and may contain a few small translucent or white particles of protein. Stelara® should not be used if the solution is discoloured or cloudy, or if foreign particulate matter is present.

Stelara® at home

- Janssen offers a free of charge service prodiving home visits from fully qualified nurses who can inject patients in their own home, or train patients to self-inject.
  In addition, the Homecare service provides a Sharps Bin Waste Disposal Service allowing patients to safely dispose of their used Stelara® pre-filled syringes.
- Registration involves the completion of a simple one-page form. If you have any questions please contact the TCP Homecare team on 1800 936 805.
- After the patient has been registered a 'Homecare Co-ordinator' will contact your patient to discuss how the service works and agree a time for a fully qualified nurse to visit them to administer the Stelara® injection or check their self-injection technique.
- This service is provided by TCP Homecare, an independent Irish company working in partnership with Janssen. TCP Homecare is a healthcare service provider, specialising in "Direct to Patient Services" which includes homecare services and sharps waste.
- It is important that the patient is able to store their medicine in a fridge until the nurse arrives to give the injection.

Contraindications[1]

- Stelara® should not be administered to patients with:
  - Hypersensitivity to the active substance (ustekinumab) or any of the excipients listed in the Summary of Product Characteristics.
  - Clinically important, active infection e.g. active tuberculosis (TB).

Special warnings and precautions[1]

- Guidelines on the use of biologics in the treatment of psoriasis suggest that patients should be screened for tuberculosis, salmonella and non-tuberculous mycobacteria.[10]
- Stelara® may have the potential to increase the risk of infections and reactivate latent infections. In clinical studies, serious bacterial, fungal, and viral infections have been observed in patients receiving Stelara®. If a patient develops a serious infection, the patient should be closely monitored and Stelara® should not be administered until the infection resolves.
- Caution should be exercised when considering the use of Stelara® in patients with a chronic infection or a history of recurrent infection.
- Prior to commencing Stelara®, patients should be screened for tuberculosis.[11]
- Patients receiving Stelara® should be monitored closely for signs and symptoms of active TB during and after treatment.
- Stelara® must not be given to patients with active TB.
- Immunosuppressants like Stelara® have the potential to increase the risk of malignancy thus appropriate history taking and monitoring is required. Caution should be exercised when considering the use of Stelara® in patients with a history of malignancy or those who develop malignancy while receiving Stelara®.
- Exfoliative dermatitis and erythrodermic psoriasis have been reported following Stelara® treatment. Symptoms of exfoliative dermatitis and erythrodermic psoriasis may be indistinguishable from each other and could be part of the natural course of the patient's disease. As part of the monitoring of the patient's plaque psoriasis, physicians should be alert to the symptoms of the skin conditions mentioned.
- Serious allergic reactions have been reported in post marketing setting, in some cases several days after treatment. Anaphylaxis and angioedema have occurred. Latex sensitivity: The needle cover on the syringe in the pre-filled syringe is manufactured from dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.
- It is recommended that live viral or live bacterial vaccines (such as Bacillus of Calmette and Guérin (BCG)) should not be given concurrently with Stelara®. Stelara® treatment should be withheld for at least 15 weeks before viral or live bacterial vaccination. Stelara® treatment should be resumed no sooner than 2 weeks after live vaccinations have been administered.
- Patients receiving Stelara® may receive concurrent inactivated or non-live vaccinations.
- In psoriasis studies, the safety and efficacy of Stelara in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of Stelara®. Caution should be exercised when considering concomitant use of other immunosuppressants and Stelara® or when transitioning from other immunosuppressive biologics.
- Stelara® has not been evaluated in patients who have undergone allergy immunotherapy. It is not known whether Stelara® may affect allergy immunotherapy.
- Stelara® is recommended for use in adolescents from the age of 12 years and older.
- Elderly patients (≥65 years): No overall differences in efficacy or safety in patients age 65 and older who received Stelara® were observed when compared to younger patients, however the number of patients aged 65 and older is not sufficient to determine whether they respond differently from younger patients. Because there is a higher incidence of infections in the elderly population in general, caution should be used in treating the elderly.
- Pregnancy should be avoided. Use effective contraception during treatment and for 15 weeks post-treatment. It is not known whether Stelara® is excreted in breast milk.

If you have any questions about Stelara® contact Janssen Medical Information on 1800 709 122.

References and prescribing information can be found on the reverse.

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Prescribing Information

STELARA® solution for injection 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 adolescent patients from the age of 12 years and older, who are inadequaely controlled by, or are intolerant to, other systemic therapies or phototherapies. **Psoriatic arthritis:** Alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **DOSAGE & ADMINISTRATION:** Under the guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis or psoriatic arthritis. Subcutaneous 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 ≤ 100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients >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 (12 years and older): Patients <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 ≥100 kg, 90mg at week 0, followed by 90mg at week 4, then every 12 weeks. **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 >100 kg. Consider discontinuation if no response after 28 weeks. ***Children <12 years:*** Not recommended. ***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. 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 past 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, they should be closely monitored and STELARA should not be administered until infection resolves. ***Malignancies:*** Potential to increase the risk of malignancy. No studies in patients with a 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. ***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 immediately. **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 has been reported following treatment. Discontinue STELARA if a drug reaction is suspected. **SIDE EFFECTS:** ***Common:*** dental infections, upper respiratory tract infection, nasopharyngitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain, antibodies to ustekinumab. ***Other side effects include:*** cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema), skin exfoliation, exfoliative dermatitis. Studies show adverse events reported in ≥12 year olds with plaque psoriasis were similar to those seen in previous studies in adults with plaque psoriasis. **Refer to SmPC for other side effects. FERTILITY:** The effect of ustekinumab has not been evaluated. **PREGNANCY:** Should be avoided. Women of childbearing potential: Use effective contraception during treatment and for at least 15 weeks post-treatment. **LACTATION:** Limited data in humans. **INTERACTIONS:** *In vitro*, STELARA had no effect on CYP450 activities. ***Vaccinations:*** Live vaccines should not be given concurrently with STELARA, and should be witheld for at least 15 weeks after last dose of STELARA. STELARA can resume at least 2 weeks after such vaccinations. No data on secondary transmission of infection by live vaccines in patients receiving STELARA. ***Concomitant immunosuppressive therapy:*** Psoriasis: The safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. **Refer to SmPC for full details of interactions. LEGAL CATEGORY:** Prescription Only Medicine. **PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER:** 45 mg: 1 x vial. EU/1/08/494/001, 45mg: 1 x 0.5ml pre-filled syringe. EU/1/08/494/003. 90mg: 1 x 1.0ml pre-filled syringe. EU/1/08/494/004. **MARKETING AUTHORISATION HOLDER:** JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. **FURTHER INFORMATION IS AVAILABLE FROM:** Janssen-Cilag Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

Prescribing information last revised: 06/2015

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie Adverse events should also be reported to Janssen-Cilag Ltd on +44 1494 567447.

References:
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Date of preparation: November 2015 PHIR/STE/1013/0004(1)a(2)

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