Clean Final combined STELARA Professional Information (PI)

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

STELARA® 45 mg solution for subcutaneous injection

STELARA® 90 mg solution for subcutaneous injection

STELARA® 130 mg solution for intravenous infusion after dilution

COMPOSITION

STELARA contains ustekinumab, a fully human IgG1κ monoclonal antibody produced in murine myeloma cell line by a recombinant DNA technology. STELARA is available in three strengths:

- 45 mg of ustekinumab in 0,5 mL
- 90 mg of ustekinumab in 1,0 mL
- 130 mg of ustekinumab in 26 mL

List of excipients:

45 mg or 90 mg Pre-filled syringe/vial

The other ingredients are: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection.

130 mg Single-use vial

The other ingredients are: EDTA disodium salt dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection.

Contains sugar (sucrose).

STELARA 45 mg subcutaneous dose contains 38 mg of sucrose.

STELARA 90 mg subcutaneous dose contains 76 mg of sucrose.

STELARA 130 mg intravenous loading dose contains 2 210 mg sucrose per vial.

PHARMACOLOGICAL CLASSIFICATION

A. 30.1 Biologics – Antibodies

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Ustekinumab is a fully human IgG1κ monoclonal antibody that binds with specificity to the shared p40 protein subunit of human cytokines interleukin (IL)-12 and IL-23. Ustekinumab inhibits the bioactivity of human IL-12 and IL-23 by preventing p40 from binding to the IL-12Rβ1 receptor protein expressed on the surface of immune cells. Ustekinumab cannot bind to IL-12 or IL-23 that is already bound to IL-12Rβ1 cell surface receptors. Thus, ustekinumab is not likely to contribute to complement or antibody mediated cytotoxicity of cells expressing IL-12 and/or IL-23 receptors.

IL-12 and IL-23 are heterodimeric cytokines secreted by activated antigen presenting cells, such as macrophages and dendritic cells. IL-12 stimulates natural killer (NK) cells and drives the differentiation of CD4+ cells toward the T-helper 1 (Th1) phenotype and stimulates interferon gamma (IFNγ) production. IL-23 induces the T helper 17 (TH17) pathway and promotes secretion of IL-17A, IL-21, and IL-22.

By binding the shared p40 subunit of IL-12 and IL-23, ustekinumab may exert its clinical effects in psoriasis**,** psoriatic arthritis and Crohn's disease through interruption of the Th1 and Th17 cytokine pathways, which are central to the pathology of these diseases.

In patients with psoriasis and /or psoriatic arthritis, ustekinumab had no apparent effect on the percentages of circulating immune cell populations including memory and naive T cell subsets or circulating cytokine levels. Systemic markers of inflammation were measurable in the serum at baseline and 4 markers (MDC, VEGF, MCSF-1 and YKL-40) showed modest differences in concentration post-treatment in ustekinumab-treated patients as compared to placebo.

In psoriasis and psoriatic arthritis studies, clinical response (improvement in Psoriasis Area and Severity Index [PASI] or ACR measurements, respectively) appeared to be related to serum ustekinumab levels. Patients with psoriasis with higher PASI response had higher median serum concentrations of ustekinumab than those with lower clinical responses.

Pharmacokinetic properties

Absorption

The median time to reach the maximum serum concentration (t_{max}) was 8,5 days after a single 90 mg subcutaneous administration in healthy subjects. The median t_{max} values of ustekinumab following a single subcutaneous administration of either 45 mg or 90 mg in patients with psoriasis were comparable to that observed in healthy subjects.

The absolute bioavailability of ustekinumab following a single subcutaneous administration was estimated to be 57,2 % in patients with psoriasis.

Distribution

Median volume of distribution during the terminal phase (Vz) following a single intravenous administration to patients with psoriasis ranged from 57 to 83 mL/kg.

Metabolism

The exact metabolic pathway for ustekinumab is unknown.

Elimination

Median systemic clearance (CL) following a single intravenous administration to patients with psoriasis ranged from 1,99 to 2,34 mL/day/kg. Median half-life ($t_{1/2}$) of ustekinumab was

approximately 3 weeks in patients with Crohn's disease, psoriasis and/or psoriatic arthritis, ranging from 15 to 32 days across all psoriasis and psoriatic arthritis studies.

Dose linearity

The systemic exposure of ustekinumab (C_{max} and AUC) increased in an approximately dose-proportional manner after a single intravenous administration at doses ranging from 0,09 mg/kg to 4,5 mg/kg or following a single subcutaneous administration at doses ranging from approximately 24 mg to 240 mg in patients with psoriasis.

Single dose versus multiple doses

Serum concentration-time profiles of ustekinumab were generally predictable after single or multiple subcutaneous dose administrations. In patients with psoriasis, steady-state serum concentrations of ustekinumab were achieved by Week 28 after initial subcutaneous doses at Weeks 0 and 4 followed by doses every 12 weeks. There was no apparent accumulation in serum ustekinumab concentration over time when given subcutaneously every 12 weeks.

In patients with Crohn's disease, following the recommended IV induction dose, median peak serum ustekinumab concentration was 126,1 mcg/mL. Starting at Week 8, subcutaneous maintenance dosing of 90 mg ustekinumab was administered every 8 or 12 weeks. Steady state ustekinumab concentration was achieved by the start of the second maintenance dose. Median steady-state trough concentrations ranged from 1,97 mcg/mL to 2,24 mcg/mL and from 0,61 mcg/mL to 0,76 mcg/mL for 90 mg ustekinumab every 8 weeks or every 12 weeks respectively.

Impact of weight on pharmacokinetics

Serum ustekinumab concentrations were affected by weight in patients with psoriasis and/or psoriatic arthritis. Within each dose (45 mg or 90 mg), patients of higher weight (>100 kg) had lower median serum ustekinumab concentrations compared with those in patients of lower weight (≤ 100 kg). However, across doses, the median trough serum concentrations of ustekinumab in patients with higher weight (> 100 kg) in the 90 mg group were comparable to those in patients with lower weight (≤ 100 kg) in the 45 mg group.

Special populations

No pharmacokinetic data are available in patients with renal insufficiency or impaired hepatic function.

No specific studies have been conducted in elderly patients. A population pharmacokinetic analysis indicated there was no apparent changes in CL/F and V/F estimates in patients ≥ 65 years.

The pharmacokinetics of ustekinumab were not affected by the use of tobacco or alcohol.

Regulation of CYP450 enzymes

The effects of IL-12 or IL-23 on the regulation of CYP450 enzymes were evaluated in an *in vitro* study using human hepatocytes, which showed that IL-12 and/or IL-23 at levels of 10 ng/mL did not alter human CYP450 enzyme activities (CYP1A2, 2B6, 2C9, 2C19, 2D6, or 3A4).

INDICATIONS

Plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy.

Psoriatic Arthritis (PsA)

STELARA, alone or in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active psoriatic arthritis in adults as second line treatment, when the response to previous Disease-Modifying Antirheumatic Drugs (DMARDS) was inadequate.

Crohn's disease

STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies.

CONTRAINDICATIONS

Hypersensitivity to ustekinumab or to any of the excipients in STELARA.

Active tuberculosis (see WARNINGS AND SPECIAL PRECAUTIONS).

WARNINGS AND SPECIAL PRECAUTIONS

Infections

STELARA is a selective immunosuppressant and may have the potential to increase the risk of infections and reactivate latent infections.

In clinical studies, serious bacterial, fungal, and viral infections were observed in patients receiving STELARA (see Side Effects: Infections).

STELARA should not be given to patients with a clinically important, active infection.

Caution should be exercised when considering the use of STELARA in patients with a chronic infection or a history of recurrent infection.

Prior to initiating treatment with STELARA, patients should be evaluated for tuberculosis infection. STELARA should not be given to patients with active tuberculosis (see Contraindications).

Treatment of latent tuberculosis infection should be initiated prior to administering STELARA. Anti-tuberculosis therapy should also be considered prior to initiation of STELARA in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving STELARA should be monitored closely for signs and symptoms of active tuberculosis during and after treatment.

Patients should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection they should be closely monitored and STELARA should not be administered until the infection resolves.

Malignancies

STELARA is a selective immunosuppressant. Immunosuppressive medicines, such as STELARA, have the potential to increase the risk of malignancy. Some patients who received STELARA in clinical studies developed cutaneous and non-cutaneous malignancies (see Side Effects: Malignancies).

STELARA has not been studied in patients with a history of malignancy. Caution should be exercised when considering the use of STELARA in patients with a history of malignancy or when considering continuing treatment in patients who develop a malignancy.

All patients, in particular those older than 60 years of age, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment, should be monitored for the appearance of non-melanoma skin cancer (see Side Effects: Malignancies).

Hypersensitivity reactions

In post-marketing experience, serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported. If an anaphylactic or other serious hypersensitivity reaction occurs, institute appropriate therapy and administration of STELARA should be discontinued

(see Side Effects: Hypersensitivity reactions).

Immunisations

Live viral or live bacterial vaccines (such as Bacillus of Calmette and Guérin (BCG)) should not be given concurrently with STELARA.

No data are available on the secondary transmission of infection by live vaccines in patients receiving STELARA. Caution is advised when administering some live vaccines to household contacts of patients receiving STELARA because of the potential risk for shedding from the household contact and transmission to the patient.

Patients receiving STELARA may receive concurrent inactivated or non-live vaccinations.

Long-term treatment with STELARA does not suppress the humoral immune response to pneumococcal polysaccharide or tetanus vaccines.

Immunosuppression

In psoriasis studies, the safety and efficacy of STELARA in combination with immunosuppressive medicines or phototherapy have not been evaluated.

In psoriatic arthritis studies, concomitant methotrexate (MTX) use did not appear to influence the safety or efficacy of STELARA. In Crohn's disease studies, concomitant use of immunomodulators (6-mercaptopurine (6-MP), azathioprine (AZA), methotrexate (MTX) or

corticosteroids did not appear to influence the safety or efficacy of STELARA.

Caution should be exercised when considering concomitant use of immunosuppressive medicines and STELARA or when transitioning from other biologic medicines. (see Interactions).

Immunotherapy

STELARA has not been evaluated in patients who have undergone allergy immunotherapy. STELARA may affect allergy immunotherapy. Caution should be exercised in patients receiving or who have received allergy immunotherapy particularly for anaphylaxis.

General: The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use of machines have been performed.

Sucrose warning:

STELARA contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take STELARA. In addition, sucrose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS

No specific interaction studies have been performed in humans. In a population pharmacokinetic analysis, the effect of the most frequently used concomitant medicines in patients with psoriasis (including paracetamol, ibuprofen, acetylsalicylic acid, metformin, atorvastatin, naproxen, levothyroxine, hydrochlorothiazide, and influenza vaccine) on pharmacokinetics of ustekinumab was explored. There were no indications of an interaction with these concomitantly administered medicines. The pharmacokinetics of STELARA was not impacted by the prior use of MTX, NSAIDs, and oral corticosteroids, or prior exposure to anti-TNFα medicines in patients with psoriatic arthritis or Crohn's disease.

In psoriasis studies, the safety and efficacy of STELARA in combination with immunosuppressive medicines, including biologics, or phototherapy have not been evaluated. Caution should be exercised when considering concomitant use of immunosuppressive medicines and STELARA.

PREGNANCY AND LACTATION

Pregnancy

The safety of STELARA has not been established during pregnancy or lactation. STELARA should not be given to a pregnant woman except if the benefit clearly outweighs the risk.

Lactation

It is unknown whether STELARA is excreted in human breast milk. Women are advised against breastfeeding while receiving STELARA.

DOSAGE AND DIRECTIONS FOR USE

Plaque psoriasis and psoriatic arthritis

For the treatment of plaque psoriasis and psoriatic arthritis, STELARA is administered by subcutaneous injection.

Adults (18-64 years):

The recommended dose of STELARA is 45 mg administered subcutaneously at Weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg (see Pharmacokinetic Properties). In patients weighing > 100 kg, 45 mg was also shown to be efficacious. However, 90 mg resulted in greater efficacy in these patients.

For patients with psoriasis, who inadequately respond to dosing every 12 weeks, consideration may be given to treating every 8 weeks.

Consideration should be given to discontinuing treatment in patients who have shown no response up to 28 weeks of treatment.

Re-treatment:

For patients with psoriasis, re-treatment with a dosing regimen of Weeks 0 and 4 after interruption of therapy has been shown to be safe and effective.

Crohn's disease

In patients with Crohn's disease, the recommended treatment regimen is a single intravenous (IV) tiered dose of STELARA based on body weight (Table 1), followed by 90 mg subcutaneous dosing 8 weeks later, then every 8 weeks thereafter (*See Instructions for use, Handling and Disposal).*

Table 1: Initial IV dosing of STELARA [a]

Body weight of patient at the time of dosing	**Dose**	**Number of 130 mg STELARA vials**
≤ 55 kg	260 mg	2
> 55 kg to ≤ 85 kg	390 mg	3
> 85 kg	520 mg	4

[a] Recommended dose (approximately 6 mg/kg)

For some patients, a single IV dose based on body weight (Table 1) followed by 90 mg subcutaneous dosing 8 weeks later, then every 12 weeks thereafter may be acceptable. Patients who inadequately respond to 90 mg subcutaneous dosing every 12 weeks may benefit from an increase in dosing frequency to every 8 weeks.

Immunomodulators and/or corticosteroids may be continued during treatment with STELARA. In patients who have responded to treatment with STELARA, corticosteroids may be reduced or discontinued in accordance with standard of care.

If therapy is interrupted, treatment may be resumed with subcutaneous dosing every 8 weeks.

Special Populations

Children and adolescents (< 18 years)

Safety and efficacy of STELARA has not been established in this age group (< 18 years old).

Elderly patients (≥ 65 years)

In clinical studies, no major age-related differences in clearance or volume of distribution were observed and no overall differences in safety and efficacy in patients age 65 and older who received STELARA were observed compared to younger patients.

Hepatic insufficiency

Specific studies have not been conducted in patients with hepatic insufficiency.

Renal insufficiency

Specific studies have not been conducted in patients with renal insufficiency.

General Consideration for subcutaneous administration

STELARA is intended for use under the guidance and supervision of a medical practitioner. A patient may self-inject with STELARA if a medical practitioner determines that it is appropriate and after proper training in subcutaneous injection technique. See Special Precautions for Disposal and Other Handling.

Comprehensive instructions for the subcutaneous administration of STELARA are given in the

Patient Information Leaflet. Patients should be instructed to inject the full amount of STELARA according to the directions provided under section 'INSTRUCTIONS FOR ADMINISTRATION' of the patient information leaflet. The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Special precautions for disposal and other handling

The solution in the STELARA vial should be visually inspected for particulate matter or discolouration prior to subcutaneous administration. The product is clear to slightly opalescent, colourless to light yellow and may contain a few small translucent or white particles of protein. This appearance is not unusual for proteinaceous solutions. The product should not be used if solution is discoloured or cloudy, or if foreign particulate matter is present. STELARA does not contain preservatives; therefore, any unused product remaining in vial and the syringe should not be used.

Unused product or waste material should be disposed of in accordance with local requirements.

Intravenous infusion (Crohn's disease)

STELARA 130 mg vials are for IV infusion only. Intravenous infusion of STELARA should be administered by qualified healthcare professionals (For preparation. see *Instructions for use, Handling and Disposal).*

Instructions for Use, Handling and Disposal

Following administration of STELARA, discard any unused portion. The syringe should be disposed of with accepted medical practices for used syringes. The syringe, needle and vial must never be re-used.

Instructions for dilution of STELARA 130 mg for IV infusion (Crohn's disease)

STELARA 130 mg solution must be diluted and prepared for IV infusion by a healthcare professional using aseptic technique.

1. Calculate the dose and the number of STELARA vials needed based on patient's body weight (see Table 1). Each 26 mL vial of STELARA contains 130 mg of ustekinumab.

2. Withdraw and then discard a volume of the 0,9% w/v sodium chloride solution from the 250 mL infusion bag equal to the volume of STELARA to be added. (Discard 26 mL sodium chloride for each vial of STELARA needed, for 2 vials-discard 52 mL, for 3 vials- discard 78 mL, for 4 vials- discard 104 mL).

3. Withdraw 26 mL of STELARA from each vial needed and add it to the 250 mL infusion bag. The final volume in the infusion bag should be 250 mL. Gently mix.

4. Visually inspect the diluted solution before administration. Do not use if visibly opaque particles, discolouration or foreign particles are observed.

5. Administer the diluted solution over a period of at least one hour. Once diluted, the infusion solution may be stored for up to four hours prior to infusion.

6. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0,2 micrometer).

7. Do not infuse STELARA concomitantly in the same intravenous line with other medicines.

8. Each vial is for single use only and any unused medicine should be disposed of in accordance with local requirements.

Storage

If necessary, the diluted infusion solution may be stored for up to four hours at room temperature. Do not freeze. Discard any unused portion of the infusion solution.

See Patient Information Leaflet for comprehensive instructions for the use, handling, and disposal.

SIDE EFFECTS

Clinical trial data

Table 2 provides a summary of adverse reactions from psoriasis, psoriatic arthritis and Crohn's disease clinical studies. The frequency of these adverse reactions was based on those that occurred during the initial controlled periods of the clinical studies. The adverse reactions are ranked by frequency, using the following convention:

Very common (≥ 1/10)

Common (≥ 1/100, <1/10)

Uncommon (≥1/1 000, <1/100)

Rare (≥ 1/10 000, <1/1 000)

Table 2 SUMMARY OF ADVERSE REACTIONS IN CLINICAL STUDIES

Infections and infestations	*Common*: Upper respiratory tract infection, nasopharyngitis *Uncommon*: Cellulitis, dental infections, herpes zoster, viral upper respiratory tract infection, vulvovaginal mycotic infection
Psychiatric disorders	*Uncommon:* Depression
Nervous system disorders	*Common:* Dizziness, headache
Respiratory, thoracic and mediastinal disorders	*Common*: Oropharyngeal pain *Uncommon:* Nasal congestion
Gastrointestinal disorders	*Common:* Diarrhoea, nausea, vomiting
Skin and subcutaneous tissue disorders	*Common:* Pruritus *Uncommon:* Acne
Musculoskeletal and connective tissue disorders	*Common:* Back pain, myalgia, arthralgia
General disorders and administration site conditions	*Common:* Fatigue, injection site erythema, injection site pain *Uncommon:* Injection site reactions (including haemorrhage, haematoma, induration, swelling and pruritus, asthenia

Physicians should consider the local disease background when treating patients with STELARA [see Warnings and Special Precautions, Infections].

Infections

In the placebo-controlled period of clinical studies of patients with psoriasis, patients with psoriatic arthritis and patients with Crohn's disease, the rate of infection was 1,38 per patient-year of follow-up in STELARA-treated patients, and 1,35 per patient-year of follow up in placebo-treated patients. Serious infections occurred at the same rate of 0,03 per patient-year of follow-up in STELARA and placebo-treated patients (see Warnings and Special Precautions: Infections).

In the controlled and non-controlled portions of psoriasis, psoriatic arthritis and Crohn's disease clinical studies, the rates of infection and serious infection were 0,91 and 0,02, respectively, per patient-year of follow-up in STELARA-treated patients. Serious infections included anal abscess, cellulites, pneumonia, diverticulitis, gastroenteritis and viral infections.

In clinical studies, patients with latent tuberculosis who were concurrently treated with isoniazid did not develop tuberculosis.

Malignancies

In the placebo controlled period of the psoriasis**,** psoriatic arthritis and Crohn's disease clinical studies, the incidence of malignancies excluding non-melanoma skin cancer was 0,12 per 100 patient-years of follow-up for STELARA-treated patients compared with 0,26 per 100 patient-

years of follow-up for placebo-treated patients.

The incidence of non-melanoma skin cancer was 0,48 per 100 patient-years of follow-up for STELARA-treated patients compared with 0,52 per 100 patient-years of follow up for placebo-treated patients.

In the controlled and non-controlled periods of psoriasis, psoriatic arthritis and Crohn's disease clinical studies malignancies, excluding non-melanoma skin cancers were reported with an incidence of 0,53 per 100 patient-years of follow-up for STELARA-treated patients. This was comparable to the incidence expected in the general population (standardised incidence ratio = 0,87 [95 % confidence interval: 0,66; 1,14]).

The most frequently observed malignancies, other than non-melanoma skin cancer, were prostate, melanoma, colorectal and breast. The incidence of non-melanoma skin cancer was 0,49 per 100 patient-years of follow-up for STELARA-treated patients. (See Warnings and Special Precautions, Malignancies).

The ratio of patients with basal versus squamous cell skin cancers (4:1) is comparable with the ratio expected in the general population.

Hypersensitivity and infusion reactions

During the controlled periods of psoriasis and psoriatic arthritis clinical studies of STELARA, rash and urticaria have each been observed in < 1 % of patients.

Post-Marketing Experience

Table 3 Post-Marketing Reports

Immune system disorders	Hypersensitivity reactions (including rash, urticaria) Serious hypersensitivity reactions (including anaphylaxis and angioedema)
Skin and subcutaneous tissue disorders	Pustular psoriasis, exfoliative dermatitis; erythrodermic psoriasis

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT

In case of overdosage, although no dose-dependent toxicity has been observed, theoretically, side effects could be exacerbated or exaggerated. It is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment be instituted immediately.

IDENTIFICATION

STELARA 45 mg and 90 mg Pre-filled syringe/vial for subcutaneous injections

The solution is clear to slightly opalescent, colourless to light yellow. The solution may contain a few small translucent or white protein particles.

STELARA 130 mg single –use vial for intravenous infusion only

The solution is clear, colourless to light yellow.

PRESENTATION

STELARA 45 mg and 90 mg subcutaneous injections are available in two presentations:

- *Single-use vial:*

  STELARA is supplied as a sterile solution in a single-use clear, colourless vial (*Type 1 glass*), closed with a grey butyl rubber stopper with a colourless Flurotec® coating and an aluminium seal with a light green flip-off cap.

- *Single-use pre-filled syringe:*

  STELARA is also supplied as a sterile solution in a single-use, clear, colourless *Type 1 glass* syringe with a fixed 27G, half-inch needle with grey rubber needle shield. The needle shield is manufactured using a dry natural rubber (*a derivative of latex*). The syringe is stoppered with a grey butyl rubber stopper with a colourless Flurotec® coating. The syringe is fitted with a passive safety guard.

STELARA is packed in an outer carton pack containing:

- 1 single-use vial or
- 1 single-use pre-filled syringe.

STELARA 130 mg single-use vial for intravenous infusion

STELARA 130 mg vial is supplied as a sterile solution in a single-use (Type 1) clear, colourless glass vial. The vial is stoppered with a grey butyl rubber coated stopper; crimped to form a tight seal between the vial and the stopper with a seal comprised of a silver aluminium shell with an attached polypropylene light green flip-off button that protects the site of injection. It is packaged as 1 single use vial in an outer container to protect from light.

STORAGE INSTRUCTIONS

Store in a refrigerator (2 ºC – 8 ºC).

Keep the vial or pre-filled syringe in the outer carton until time of use in order to protect from light.

Do not freeze. Do not shake.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS

STELARA 45 mg and 90 mg: 43/30.1/0727 – 0728

STELARA 130 mg: 51/30.1/0851

NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION LEAFLET

- Date of registration of STELARA 45 mg and 90 mg: 27 July 2012
- Date of registration of STELARA 130 mg: 9 December 2019
- Date of most recently revised professional information leaflet as approved by Council: 9 December 2019