Approved Professional Information (PI)

SCHEDULING STATUS
Schedule 4

1. NAME OF THE MEDICINE

STELARA® 45 mg solution for subcutaneous injection

STELARA® 90 mg solution for subcutaneous injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe contains:

- 45 mg ustekinumab in 0,5 mL

- 90 mg ustekinumab in 1,0 mL

Each vial contains:

- 45 mg ustekinumab in 0,5 mL

Ustekinumab is a fully human IgG1κ monoclonal antibody to interleukin (IL) -12/23 produced in a murine myeloma cell line using recombinant DNA technology.

For the full list of excipients, see section 6.1.

Contains sugar (sucrose).

STELARA 45 mg subcutaneous dose contains 38 mg of sucrose.

STELARA 90 mg subcutaneous dose contains 76 mg of sucrose.

3. PHARMACEUTICAL FORM

Solution for injection.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic 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.

Paediatric plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

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.

Ulcerative colitis

STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or

were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

4.2 Posology and method of administration

Posology

STELARA is intended for use under the guidance and supervision of medical practitioners experienced in the diagnosis and treatment of conditions for which STELARA is indicated.

Posology

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 section 5.2, 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 and Ulcerative Colitis

In the treatment regimen, the first dose of STELARA is administered intravenously. For the posology of the intravenous dosing regimen, see section 4.2 of the STELARA 130 mg Concentrate for solution for infusion Professional information.

The first subcutaneous administration of 90 mg STELARA should take place at week 8 after the intravenous dose. After this, dosing every 12 weeks is recommended.

Patients who have not shown adequate response at 8 weeks after the first subcutaneous dose, may receive a second subcutaneous dose at this time.

Patients who lose response on dosing every 12 weeks may benefit from an increase in dosing frequency to every 8 weeks.

Patients may subsequently be dosed every 8 weeks or every 12 weeks according to clinical judgement.

Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit 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 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.

In Crohn's disease or ulcerative colitis, if therapy is interrupted, resumption of treatment with subcutaneous dosing every 8 weeks is safe and effective.

Elderly (≥ 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. The number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients.

No dose adjustment is needed for elderly patients (see section 4.4).

Renal and hepatic impairment

STELARA has not been studied in these patient populations. No dose recommendations can be made.

Paediatric population

The safety and efficacy of STELARA in children with psoriasis less than 6 years of age or in children with psoriatic arthritis less than 18 years of age have not yet been established.

The safety and efficacy of STELARA in treatment of Crohn's disease or ulcerative colitis in children less than 18 years of age have not been established.

Paediatric plaque psoriasis (6 years and older)

For the treatment of plaque psoriasis, STELARA should be administered by subcutaneous injection. The recommended dose of STELARA based on body weight is shown below (Tables 1 and 2). STELARA should be administered at Weeks 0 and 4, then every 12 weeks thereafter.

Table 1: Recommended dose of STELARA for paediatric psoriasis		
Weight	**Recommended dose**	**Dosage form**
< 60 kg	0,75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Pre-filled syringe, vial
>100 kg	90 mg	Pre-filled syringe
* To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: *body weight* (kg) x *0,0083* (mL/kg) or see Table 2. The calculated volume should be rounded to the nearest 0,01 mL and administered using a 1 mL graduated syringe. A 45 mg vial is available for paediatric patients who need to receive less than the full 45 mg dose.		

Table 2 Injection volumes of STELARA for paediatric psoriasis patients < 60 kg

Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33

41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

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

Method of administration

STELARA 45 mg vials or 45 mg and 90 mg pre-filled syringes are for subcutaneous injection only. If possible, areas of the skin that show psoriasis should be avoided as injection sites.

After proper training in subcutaneous injection technique, patients or their caregivers may inject STELARA if a medical practitioner determines that it is appropriate. In paediatric patients, it is recommended that STELARA be administered by a healthcare provider. However, the medical practitioner should ensure appropriate follow-up of patients. Patients or their caregivers should be instructed to inject the prescribed amount of STELARA according to the directions provided in the Professional information. Comprehensive instructions for administration are given in the Patient Information Leaflet.

For further instructions on the preparation and special precautions for handling, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance, ustekinumab, or to any of the excipients listed in section 6.1.

Active tuberculosis (see section 4.4).

4.4 Special warnings and precautions for use

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 section 4.8: 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 section 4.3). 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 section 4.8: 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 section 4.8: 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 section 4.8: Hypersensitivity reactions).

Latex sensitivity

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

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.

Infant exposure *in utero*

For infants exposed *in utero* to ustekinumab, a six month waiting period following birth is recommended before the administration of live vaccines. Administration of a live vaccine prior to 6 months of age may be considered if ustekinumab dosing was limited to the first trimester of pregnancy when placental transport is minimal, or ustekinumab serum levels are undetectable in the infant, or the benefit of the vaccination clearly outweighs the theoretical risk of administration of live vaccines to the infant (see section 4.6 - Fertility, pregnancy and lactation).

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 and ulcerative colitis 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 section 4.5).

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.

Sucrose

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

4.5 Interaction with other medicinal products and other forms of interaction

Live vaccines should not be given concurrently with STELARA. Recommendations for infants exposed to ustekinumab *in utero* are provided (see section 4.4).

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, Crohn's disease or in patients with ulcerative colitis.

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.

4.6 Fertility, 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

Limited data from published literature suggests that ustekinumab is excreted in human breast milk in very small amounts. While systemic exposure to the breastfed infant is expected to be low because ustekinumab is a large molecule and is degraded in the gastrointestinal tract, it is not known if STELARA is absorbed systemically after ingestion. Women are advised against breastfeeding while receiving STELARA.

Fertility

The effect of STELARA on human fertility has not been evaluated (see section 5.3).

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Clinical studies experience in adult patients

Summary of safety profile

The most common adverse reactions (> 5 %) in controlled periods of the adult psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies with STELARA were nasopharyngitis and headache. Most were considered to be mild and did not necessitate discontinuation of study treatment. The most serious adverse reaction that has been reported for STELARA is serious hypersensitivity reactions including anaphylaxis (see section 4.4). The overall safety profile was similar for patients with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

Tabulated list of adverse reactions

The safety data described below reflect exposure in adults to STELARA in 14 phase 2 and phase 3 studies in 6 709 patients (4 135 with psoriasis and/or psoriatic arthritis, 1 749 with Crohn's disease and 825 patients with ulcerative colitis). This includes exposure to STELARA in the controlled and non-controlled periods of the clinical studies for at least 6 months or 1 year (4 577 and 3 253 patients respectively with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis) and exposure for at least 4 or 5 years (1 482 and 838 patients with psoriasis respectively).

Table 3 provides a list of adverse reactions from adult psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies. The adverse reactions are classified by System Organ Class and frequency, using the following convention: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1 000 to < 1/100), Rare (≥ 1/10 000 to < 1/1 000), Very rare (< 1/10 000), not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 3: Summary of Adverse Reactions in Clinical Studies

System Organ Class	**Frequency: Adverse reaction**
Infections and infestations	*Common*: Upper respiratory tract infection, nasopharyngitis, sinusitis *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 section 4.4).

Description of selected adverse reactions

Infections

In the placebo-controlled period of clinical studies of patients with psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis, the rate of infection was 1,36 per patient-year of follow-up in STELARA-treated patients, and 1,34 per patient 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 section 4.4: Infections).

In the controlled and non-controlled portions of psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis 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, cellulitis, 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, Crohn's disease and ulcerative colitis clinical studies, the incidence of malignancies excluding non-melanoma skin cancer was 0,11 per 100 patient-years of follow-up for STELARA-treated patients compared with 0,23 per 100 patient years of follow up for placebo-treated patients.

The incidence of non-melanoma skin cancer was 0,43 per 100 patient-years of follow-up for STELARA-treated patients compared with 0,46 per 100 patient-years of follow up for placebo-treated patients.

In the controlled and non-controlled periods of psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies malignancies, excluding non-melanoma skin cancers were reported with an incidence of 0,54 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 = 0,93 [95% confidence interval: 0,71, 1,20]).

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 section 4.4: Malignancies).

The ratio of patients with basal versus squamous cell skin cancers (3:1) is comparable with the ratio expected in the general population.

Hypersensitivity

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

Clinical studies experience in paediatric patients with psoriasis

The safety of STELARA has been studied in two Phase 3 studies of paediatric patients with moderate to severe plaque psoriasis. The first study was in 110 patients from 12 to 17 years of age treated for up to 60 weeks (CADMUS) and the second study was in 44 patients from 6 to 11 years of age treated for up to 56 weeks (CADMUS Jr.). In general, the adverse events reported in these two studies were similar to those seen in previous studies in adults with plaque psoriasis.

Postmarketing experience

Table 4: Adverse Reactions Identified During Postmarketing Experience with STELARA

Immune system disorders	Hypersensitivity reactions (including rash, urticaria) Serious hypersensitivity reactions (including anaphylaxis, angioedema)
Infections and infestations	Lower respiratory tract infection
Respiratory, thoracic and mediastinal disorders	Allergic alveolitis, eosinophilic pneumonia
Skin and subcutaneous tissue disorders	Pustular psoriasis, exfoliative dermatitis, erythrodermic psoriasis, hypersensitivity vasculitis

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA

via the :**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

In case of overdose, 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Immunosuppressants, interleukin inhibitors, ATC code: L04AC05.

Mechanism of action

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 complement or antibody mediated cytotoxicity of cells with 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, Crohn's disease and ulcerative colitis 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.

In patients with Crohn's disease and ulcerative colitis, treatment with ustekinumab resulted in a decrease in inflammatory markers including C-Reactive Protein (CRP) and faecal calprotectin during the induction phase, which were then maintained throughout the maintenance phase.

5.2 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 ulcerative colitis, 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 and ulcerative colitis, following the recommended IV induction dose, median peak serum ustekinumab concentration was 126,1 mcg/mL in patients with Crohn's disease and 127,0 mcg/mL in patients with ulcerative colitis. 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 impaired renal or 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.

Paediatrics (17 years of age and younger)

The pharmacokinetics of ustekinumab in paediatric psoriasis patients, 6 to 17 years of age, treated with the recommended dose was generally comparable to that in the adult psoriasis population.

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).

5.3 Preclinical safety data

Non-clinical data reveal no special hazard (e.g. organ toxicity) for humans based on studies of repeated-dose toxicity and developmental and reproductive toxicity, including safety pharmacology evaluations. In developmental and reproductive toxicity studies in cynomolgus monkeys, neither adverse effects on male fertility indices nor birth defects or developmental toxicity were observed. No adverse effects on female fertility indices were observed using an analogous antibody to IL-12/23 in mice.

Dose levels in animal studies were up to approximately 45-fold higher than the highest equivalent dose intended to be administered to psoriasis patients and resulted in peak serum concentrations in monkeys that were more than 100-fold higher than observed in humans.

Carcinogenicity studies were not performed with ustekinumab due to the lack of appropriate models for an antibody with no cross-reactivity to rodent IL-12/23 p40.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-histidine

L-histidine monohydrochloride monohydrate

Polysorbate 80

Sucrose

Water for injection

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

STELARA 45 mg solution for injection

0,5 mL solution in a type I glass 2 mL vial closed with a coated butyl rubber stopper.

STELARA 45 mg solution for injection in pre-filled syringe

0,5 mL solution in a type I glass 1 mL syringe with a fixed stainless steel needle and a needle cover containing dry natural rubber (a derivative of latex). The syringe is fitted with a passive safety guard.

STELARA 90 mg solution for injection in pre-filled syringe

1 mL solution in a type I glass 1 mL syringe with a fixed stainless steel needle and a needle cover containing dry natural rubber (a derivative of latex). The syringe is fitted with a passive safety guard.

STELARA is available in a 1 vial pack or a pack of 1 pre-filled syringe.

6.6 Special precautions for disposal and other handling

The solution in the STELARA vial or pre-filled syringe should not be shaken. The solution should be visually inspected for particulate matter or discolouration prior to subcutaneous administration. The solution 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 medicine should not be used if the solution is discoloured or cloudy, or if foreign particulate matter is present. Before administration, STELARA should be allowed to reach room temperature (approximately half an hour). Detailed instructions for use are provided in the Patient Information Leaflet.

STELARA does not contain preservatives; therefore any unused medicine remaining in the vial and the syringe should not be used. STELARA is supplied as a sterile, single-use vial or single-use pre-filled syringe. The syringe, needle and vial must never be re-used. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION



JANSSEN PHARMACEUTICA (Pty) Ltd

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8. REGISTRATION NUMBER(S)

STELARA 45 mg: 43/30.1/0727

STELARA 90 mg: 43/30.1/0728

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration of STELARA 45 mg and 90 mg: 27 July 2012

10. DATE OF REVISION OF THE TEXT

24 August 2023

Approved Patient Information Leaflet (PIL)

SCHEDULING STATUS
Schedule 4

STELARA® 45 mg solution for injection (vials & pre-filled syringes)

STELARA® 90 mg solution for injection (pre-filled syringes)

Ustekinumab

Contains sugar (sucrose).

STELARA 45 mg subcutaneous dose contains 38 mg of sucrose.

STELARA 90 mg subcutaneous dose contains 76 mg of sucrose.

Read all of this leaflet carefully before you start using STELARA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- STELARA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What STELARA is and what it is used for
2. What you need to know before you use STELARA
3. How to use STELARA
4. Possible side effects
5. How to store STELARA
6. Contents of the pack and other information

1. What STELARA is and what it is used for

STELARA contains the active substance ‘ustekinumab’, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

STELARA belongs to a group of medicines called ‘immunosuppressants’. These medicines work by weakening part of the immune system.

What STELARA is used for

STELARA is used to treat the following inflammatory diseases:

- Plaque psoriasis - in adults and children aged 6 years and older
- Psoriatic arthritis - in adults
- Moderate to severe Crohn’s disease - in adults
- Moderate to severe ulcerative colitis - in adults

Plaque psoriasis

STELARA is intended for the treatment of moderate to severe plaque psoriasis in adults and children aged 6 years and older. Plaque psoriasis is an inflammatory disease of the skin and nails.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you don't respond well enough to these medicines, you may be given STELARA.

Crohn's disease

Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given STELARA to reduce the signs and symptoms of your disease.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given STELARA to reduce the signs and symptoms of your disease.

2. What you need to know before you use STELARA

Do not use STELARA

- **if you are hypersensitive (allergic)** to ustekinumab or any of the other ingredients in STELARA (listed in section 6).
- if you have **tuberculosis (TB**).

Warnings and precautions

Tell your doctor or health care provider before being given an injection:

Talk to your doctor or pharmacist before using STELARA. Your doctor will check how well you are before treatment. Make sure you tell your doctor about any illness you have before treatment. Also tell your doctor if you have recently been near anyone who might have tuberculosis. Your doctor will examine you and do a test for tuberculosis, before you have STELARA. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

Look out for serious side effects

STELARA can cause serious side effects, including allergic reactions and infections. You must look out for certain signs of illness while you are taking STELARA. See 'Serious side effects' in section 4 for a full list of these side effects.

Take special care with STELARA:

Tell your doctor about all of your medical conditions before each treatment, including if you:

- **Ever had an allergic reaction to STELARA**. Ask your doctor if you are not sure.
- **Have any kind of infection** even if it is very minor, or have any signs of an infection. This could include fever, tiredness, cough, flu-like symptoms, diarrhoea, dental problems and burning on urination. Also, tell your doctor if you have any open cuts or sores, have an infection that won't go away or a history of an infection that keeps coming back. This is important because STELARA may lower your ability to fight infections. Some infections could become serious and lead to hospitalisation;
- **Have or have had any type of cancer**. Medicines such as STELARA that decrease the activity of the immune system, may increase the risk of cancer.
- **Have any new or changing lesions** within psoriasis areas or on normal skin.
- **Have recently received or are scheduled to receive a vaccine**. Tell your doctor if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system, and can cause serious problems.
- **Are having or have ever had injections to treat allergies** – it is not known if STELARA may affect these.
- **If you ever had an allergic reaction to latex or STELARA injection** - The container of the pre-filled syringe contains latex rubber, which may cause severe allergic reactions in people who are sensitive to latex.
- **If you are having any other treatment therapies** – such as immunosuppressive medicine (a medicine that inhibits the actions of your immune system) or phototherapy

(when your body is treated with specific Ultra Violet light) while using STELARA. STELARA has an effect on your immune system and the combination of these therapies may increase the risk of diseases related to a weakened immune system. However, the combination of these therapies has not been investigated.

- **Are pregnant, planning to become pregnant, or breastfeeding.** STELARA should only be used during pregnancy, if needed. STELARA may pass into your breast milk in very small amounts. Women who are breastfeeding should talk to their doctor about whether or not to use STELARA.

Your doctor will assess your health before treatment. Tell your doctor about all of your medical conditions.

Children and adolescents

STELARA is not recommended for children with psoriasis under 6 years of age, or for use in children under 18 years of age with psoriatic arthritis, Crohn's disease or ulcerative colitis because it has not been studied in this age group.

Other medicines, vaccines and STELARA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist:

- if you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using STELARA.

If you used STELARA while pregnant, tell your baby's doctor about your STELARA use before the baby receives any vaccine, including live vaccines, such as BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any live vaccines.

STELARA with food and drink

STELARA can be used with or without food or drink.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

The effects of STELARA in pregnant women are not known. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using STELARA.

Driving and using machines

It is not known if STELARA will affect the ability to drive or use machines.

STELARA contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using STELARA. STELARA contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How STELARA will be given

STELARA is intended for the use under the guidance and supervision of a doctor experienced in treating conditions for which STELARA is intended.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Talk to your doctor about when you will have your injections and follow-up appointments.

Your doctor will tell you how long treatment with STELARA will last. Do not stop treatment early because your symptoms may return. If you have the impression that the

effect of STELARA is too strong or too weak for you, tell your doctor or pharmacist.

How much STELARA is given

Your doctor will decide how much STELARA you need to receive and for how long.

Adults aged 18 years or older

Psoriasis and Psoriatic Arthritis

- The recommended starting dose is 45 mg STELARA. Patients who weigh more than 100 kilograms (kg) may start on a dose of 90 mg instead of 45 mg.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks. The following doses are usually the same as the starting dose.

Crohn's disease or Ulcerative colitis

- During treatment, the first dose of approximately 6 mg/kg STELARA will be given by your doctor through a drip in a vein in your arm (intravenous infusion). After the starting dose, you will receive the next dose of 90 mg STELARA after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously').
- In some patients, after the first injection under the skin, 90 mg STELARA may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

Children and adolescents aged 6 years or older

<u>Psoriasis</u>

- The doctor will work out the right dose for you, including the amount (volume) of STELARA to be injected to give the right dose. The right dose will depend on your body weight at the time each dose is given.
- A 45 mg vial is available for children who need to receive less than the full 45 mg dose.

- If you weigh less than 60 kg, the recommended dose is 0,75 mg of STELARA per kg body weight.
- If you weigh 60 kg to 100 kg, the recommended dose is 45 mg STELARA.
- If you weigh more than 100 kg, the recommended dose is 90 mg STELARA.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks.

How STELARA is given

- STELARA is given as an injection under the skin ('subcutaneously'). At the start of your treatment, medical or nursing staff may inject STELARA.
- However, you and your doctor may decide that you may inject STELARA yourself. In this case you will get training on how to inject STELARA yourself.
- For instructions on how to inject STELARA, see 'Instructions for administration' at the end of this leaflet.

Talk to your doctor if you have any questions about giving yourself an injection.

If you use more STELARA than you should

If you have used or been given too much STELARA, talk to a doctor or pharmacist straight away. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to use STELARA

If you forget a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you stop using STELARA

It is not dangerous to stop using STELARA. However, if you stop, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor or

pharmacist.

4. Possible side effects

STELARA can cause side effects.

Not all side effects reported for STELARA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving STELARA, please contact your health care provider for advice.

If you experience any of the following side effects, tell your doctor immediately or go to the casualty department at your nearest hospital:

- ***Infections (including tuberculosis)*** - signs of infection include: fever, tiredness, (persistent) cough, shortness of breath, flu-like symptoms, night sweats, diarrhoea, wounds, dental problems and burning on urination.
- ***Allergic reaction*** - signs of serious allergic reactions (anaphylaxis) include: skin rash; hives; swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing; low blood pressure, which can cause dizziness or light-headedness; swelling of the hands, feet or ankles. In rare cases, symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction to STELARA.
  If you have a serious allergic reaction, your doctor may decide that you should not use STELARA again.

These are all serious side effects. You may need urgent medical attention.

Other side effects that have been observed with STELARA are included below. Tell your doctor if you experience any of these side effects.

Frequently reported side effects:

- Diarrhoea
- Tiredness
- Dizziness
- Headache
- Itching
- Back or muscle pain
- Sore throat
- Redness and pain where the injection is given
- Nausea
- Joint pain
- Vomiting
- Sinus infection.

Less frequently reported side effects:

- Depression
- Blocked or stuffy nose
- Inflammation of tissue under the skin ('cellulitis'), showing as warmth, swelling, redness, and pain of the skin
- Pain, swelling, itching, hardness, bleeding, bruising and irritation at the injection site
- Shingles (a type of painful rash with blisters)
- Pustular psoriasis (a change in psoriasis where redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever)
- An increase in redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis)
- Peeling of the skin (skin exfoliation)
- Fungal infection (thrush) of the vulva and vagina
- Acne

- Loss of strength, weakness, or lack of energy (asthenia)
- Dental infections
- Inflammation of small blood vessels, which can lead to skin rash with small red or purple bumps, fever or joint pain (vasculitis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of STELARA.

5. How to store STELARA

Store all medicine out of reach of children.

Store in a refrigerator (2 °C – 8 °C). Do not freeze STELARA.

Do not use STELARA if you know, or think, that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

Keep the product in the original outer carton in order to protect the solution from light.

Do not shake STELARA vials or pre-filled syringes. Prolonged vigorous shaking may damage the product. Do not use the product if it has been shaken vigorously.

Do not use STELARA after the expiry date, which is stated on the label and the carton after "EXP". The expiry date refers to the last day of that month.

Do not use STELARA if the seal is broken.

The solution 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 solutions containing protein. Do not use STELARA if the liquid is discoloured, cloudy or you can see other foreign particles floating in it.

Do not mix STELARA with other liquids for injection.

STELARA is for single use only. Any unused product remaining in the vial and the pre-filled syringe should be thrown away.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What STELARA contains

- The active substance is ustekinumab. Each vial or pre-filled syringe contains 45 mg ustekinumab in 0,5 mL or 90 mg ustekinumab in 1,0 mL.
- The other ingredients are L-histidine, L-histidine monohydrochloride monohydrate, 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.

What STELARA looks like and contents of the pack

STELARA is a clear to slightly opalescent (having a pearl-like shine), colourless to light yellow solution for injection. The solution may contain a few small translucent or white particles of protein.

It is supplied as a carton pack containing 1 single-dose, glass 2 mL vial. Alternatively, it is

supplied as a carton containing 1 single-dose, glass 1 mL pre-filled syringe.

Each vial or pre-filled syringe contains 45 mg ustekinumab in 0,5 mL or 90 mg ustekinumab in 1 mL of solution for injection.

Holder of Certificate of Registration



JANSSEN PHARMACEUTICA (PTY) LTD

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This leaflet was last revised in

Date of registration of STELARA 45 mg and 90 mg: 27 July 2012

Date of revision of text: 24 August 2023

Registration numbers

STELARA 45 mg: 43/30.1/0727

STELARA 90 mg: 43/30.1/0728

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.

FURTHER INFORMATION

INSTRUCTIONS FOR ADMINISTRATION

At the start of your therapy, STELARA may be injected by medical or nursing staff. However, your doctor may decide that you may inject STELARA yourself. In this case, you will receive training on how to inject STELARA. Call your doctor if you have any questions about giving yourself an injection.

STELARA is not to be mixed with other liquids for injection.

INSTRUCTIONS FOR INJECTING STELARA FROM A VIAL:

Do not shake STELARA vials. Prolonged vigorous shaking may damage the product. Do not use the product if it has been shaken vigorously.

1. Check vials and assemble materials:

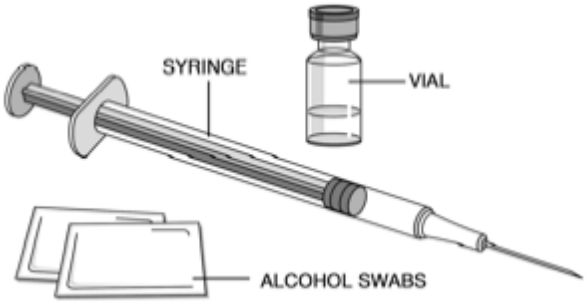
Take the vial out of the refrigerator. Let the vial stand for about half an hour. This will let the liquid come to a comfortable temperature for injection (room temperature).

If your dose is 45 mg you will receive one 45 mg vial of STELARA. If your dose is 90 mg, you will receive either one 90 mg vial of STELARA or two 45 mg vials of STELARA and you will need to give yourself two injections. Choose two different sites for these injections (for example one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other. Use a new needle and syringe for each injection.

- Check the vial(s), to make sure that it is the right product (i.e. number of vials and strength is correct), has not passed its expiration date.
- Make sure the vial is not damaged, and the seal is not broken, and the liquid is clear to slightly opalescent and colourless to slightly yellow. DO NOT use if it is frozen, discoloured, cloudy or contains large particulates.

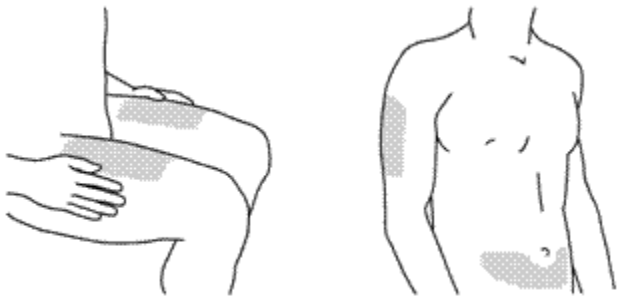
Thoroughly wash your hands with soap and warm water.

• Assemble and lay out on a clean surface everything you need such as a syringe, needle and antiseptic swabs



2. Choosing and preparing the injection site:

• Choose an injection site. STELARA is given by injection under the skin (subcutaneously). Good sites for the injection are the upper thigh or around the belly (abdomen) at least 5 centimeters away from the navel. Avoid, if possible, areas of skin that already show symptoms of psoriasis. If someone will assist in giving you the injection, then he/she may also choose the upper arms or buttocks as injection site.

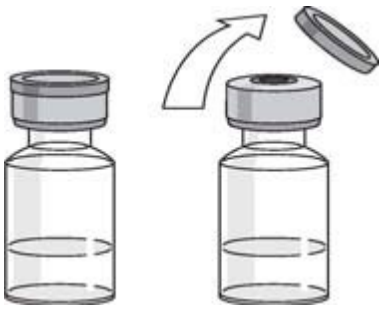


*Areas in gray are recommended injection sites.

• Preparing injection site. Wipe the injection site with an alcohol swab. **DO NOT** touch this area again before giving the injection.

3. Preparing the dose:

• Remove the cap from the top of the vial but do not remove the stopper.



• Clean the stopper with an antiseptic swab.

• Remove the needle cover. Do not touch the needle or allow the needle to touch anything.

• Put the vial on a flat surface and push the syringe needle through the rubber stopper.

• Turn the vial and the syringe upside down. Pull on the syringe plunger to fill the syringe with the amount of liquid prescribed by your doctor (0,5 mL - 1,0 mL). It is important that the needle is always in the liquid in order to prevent air bubbles forming in the syringe.



• Remove the needle from the vial. Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.



4. Injecting the dose:

• Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.

• Push the syringe needle into the pinched skin.

• Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.



• When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

• Dispose of your used syringe in a safe container and dispose of your vial. See section 5 " How to store STELARA".

5. After the injection:

- Press an antiseptic wipe over the injection site for a few seconds after the injection.
- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- Do not rub the skin at the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

6. Disposal:

- Used syringes and needles should be placed in a puncture-resistant container, like a sharps container. Never re-use needles and syringes, for your safety and health, and for the safety of others. Dispose of your sharps container according to your local regulations

Empty vials, antiseptic wipes, and other supplies can be disposed of in your garbage.

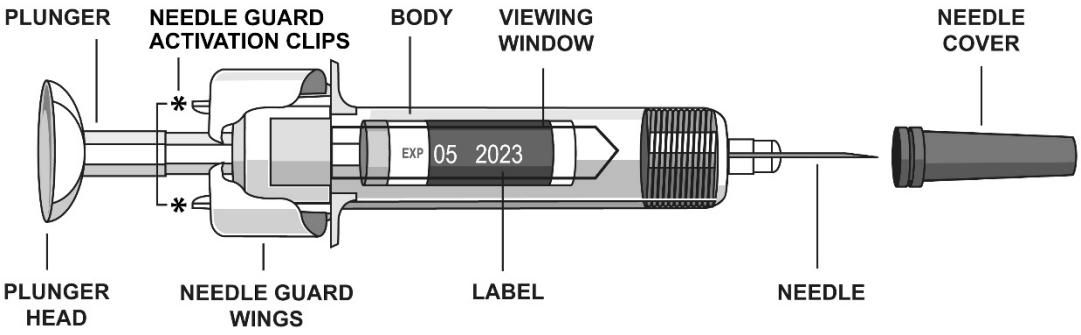
INSTRUCTIONS FOR INJECTING STELARA USING A PRE-FILLED SYRINGE

At the start of treatment, your health care provider will assist you with your first injection. However, you and your doctor may decide that you may inject STELARA yourself. If this happens, you will get training on how to inject STELARA. Talk to your doctor if you have any questions about giving yourself an injection.

- Do not mix STELARA with other liquids for injection
- Do not shake STELARA pre-filled syringes. This is because strong shaking may damage the medicine. Do not use the medicine if it has been shaken strongly.

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

1. Preparing for pre-filled syringe use

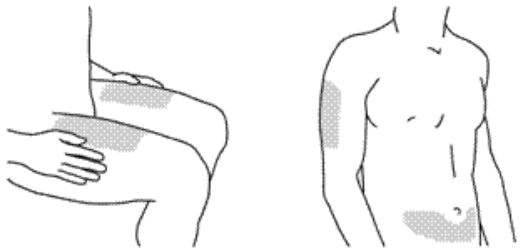


- Take the pre-filled syringe(s) out of the refrigerator. Let the pre-filled syringe stand outside the box for about half an hour. This will let the liquid come to a comfortable temperature for injection (room temperature). Do not remove the syringe's needle cover while allowing it to reach room temperature.
- Check the package to make sure that it is the right dose (i.e. that the number of pre-filled syringes and strength is correct).
    - If your dose is 45 mg you will get one 45 mg pre-filled syringe of STELARA
    - If your dose is 90 mg you will get two 45 mg pre-filled syringes of STELARA or one 90 mg pre-filled syringe of STELARA and you will need to give yourself two injections. Choose two different sites for these

injections (e.g. one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other.

- Open the box and remove the pre-filled syringe. Check the expiration date on the pre-filled syringe and the label of the box. If the expiration date has passed, don't use it.
- Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.
- Hold the pre-filled syringe with the covered needle pointing upward.
- Do not hold by the plunger head, plunger, needle guard wings, or needle cover.
- Make sure the syringe is not damaged. Look at the solution or liquid in the syringe to make sure that it is clear to slightly opalescent and colourless to slightly yellow. **DO NOT** use if it is frozen, discoloured, cloudy or contains large particles and contact your healthcare provider for assistance.
- **DO NOT** remove the needle cover from the pre-filled syringe until instructed to do so.
- **DO NOT** pull back on the plunger head at any time.
- **DO NOT** touch the needle guard activation clips (as indicated by asterisks * in Figure above) to prevent pre-maturely covering the needle with the needle guard.

2. Choosing and preparing the injection site

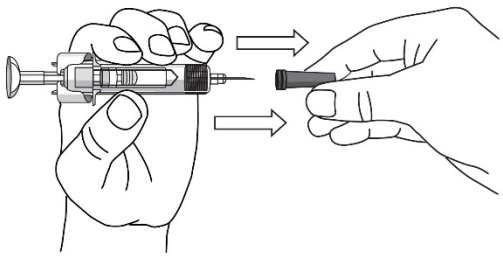


*Areas in gray are recommended injection sites.

- STELARA is given by injection under the skin (subcutaneously).
- Good sites are the top of the thigh and around the tummy (abdomen) but about 5 cm away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms as well.
- Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3. Remove the needle cover

- The needle cover should **not** be removed until you are ready to inject the dose
- Pick up the pre-filled syringe, hold the body of the syringe with one hand
- Pull the needle cover straight off and throw it away. Do not touch the plunger while you do this

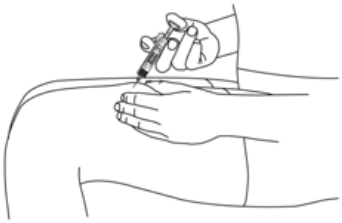


- You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal and do not need to be removed. Do not touch the needle or allow it to touch any surface. **Note:** The needle cover should **NOT** be removed until you are ready to inject the dose.
- Do not use pre-filled syringe if it is dropped without the needle cover in place. If you drop the syringe without the needle cover in place, please contact your health care provider for assistance. Inject the dose promptly after removing the needle cover.

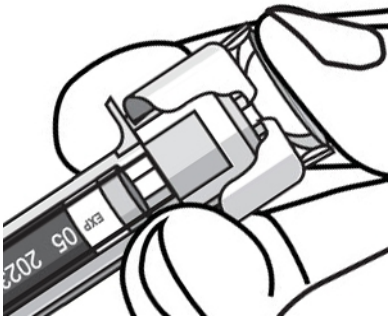
4. Injecting the dose

- Hold the pre-filled syringe with one hand between the middle and index fingers and place the thumb on top of the plunger head and use the other hand to gently pinch the cleaned skin between your thumb and index finger. Do not squeeze it tightly.
- Do not pull back on the plunger at any time.

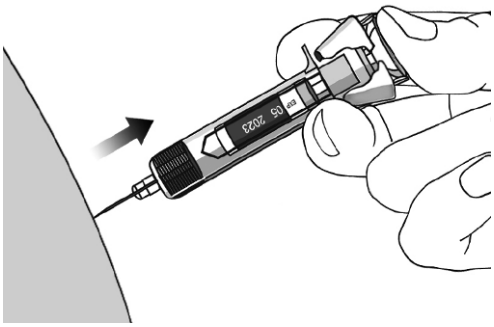
In a single and swift motion, insert the needle through the skin as far as it will go.



- Inject all of the medication by pushing in the plunger until the plunger head is completely between the needle guard wings.



- When the plunger is pushed as far as it will go, continue to keep the pressure on the plunger head, take out the needle and let go of the skin.



- Slowly take your thumb off the plunger head to allow the empty syringe to move up until the entire needle is covered by the needle guard, as shown below.

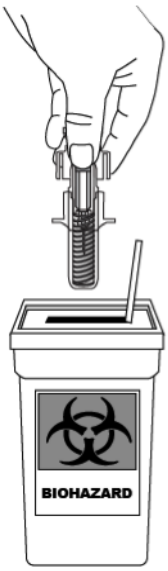


5. After the injection

- Press an antiseptic wipe over the injection site for a few seconds after the injection.
- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- Do not rub the skin at the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

6. Disposal:

- Used syringes should be placed in a puncture-resistant container, like a sharps container (see below). Never re-use a syringe, for your safety and health and for the safety of others. Dispose of your sharps container according to your local regulations
- Antiseptic wipes and other supplies can be disposed of in your garbage.



Goedgekeurde Pasiëntinligtingsbiljet (PIB)

SKEDULERINGSTATUS
Skedule 4

STELARA® 45 mg oplossing vir inspuiting (flessies & voorafgevulde spuite)

STELARA® 90 mg oplossing vir inspuiting (voorafgevulde spuite)

Ustekinumab

Bevat suiker (sukrose).

STELARA 45 mg onderhuidse dosis bevat 38 mg sukrose.

STELARA 90 mg onderhuidse dosis bevat 76 mg sukrose.

Lees hierdie hele biljet noukeurig voordat u STELARA begin gebruik

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Vra asseblief vir u dokter, apteker, verpleegkundige of ander verskaffer van gesondheidsorg as u nog vrae het.
- STELARA is vir u persoonlik voorgeskryf en u moet u medisyne nie met ander mense deel nie. Dit kan hulle leed berokken, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie biljet is

1. Wat STELARA is en waarvoor dit gebruik word
2. Wat u moet weet voordat u STELARA gebruik
3. Hoe om STELARA te gebruik
4. Moontlike newe-effekte
5. Hoe om STELARA te berg
6. Inhoud van die pakkie en ander inligting

1. Wat STELARA is en waarvoor dit gebruik word

STELARA bevat die aktiewe bestanddeel ‘ustekinumab’, ’n monoklonale teenliggaampie. Monoklonale teenliggaampies is proteïene wat sekere proteïene in die liggaam herken en spesifiek daaraan bind.

STELARA behoort aan ’n groep medisynes wat ‘immuunonderdrukkers’ genoem word. Hierdie medisynes werk deur ’n gedeelte van die immuunstelsel te verswak.

Waarvoor STELARA gebruik word

STELARA word gebruik om die volgende inflammatoriese siektes te behandel:

- Plaakpsoriase – in volwassenes en kinders wat 6 jaar oud en ouer is
- Psoriatiese artritis – in volwassenes
- Matige tot erge Crohn se siekte – in volwassenes
- Matige tot erge ulseratiewe kolitis – in volwassenes

Plaakpsoriase

STELARA is bedoel vir die behandeling van matige tot erge plaakpsoriase in volwassenes en kinders wat 6 jaar oud en ouer is. Plaakpsoriase is ’n inflammatoriese siekte van die vel en naels.

Psoriatiese artritis

Psoriatiese artritis is ’n inflammatoriese siekte van die gewrigte, wat gewoonlik met psoriase gepaard gaan. As u aktiewe psoriatiese artritis het, sal u eers ander medisynes kry. As u nie goed genoeg op hierdie medisynes reageer nie, kan u STELARA kry.

Crohn se siekte

Crohn se siekte is ’n inflammatoriese siekte van die derm. As u Crohn se siekte het, sal u eers ander medisynes kry. As u nie goed genoeg reageer nie of hierdie medisynes nie

kan verdra nie, kan u STELARA kry om die tekens en simptome van u siekte te verminder.

Ulseratiewe kolitis

Ulseratiewe kolitis is ’n inflammatoriese siekte van die derm. As u ulseratiewe kolitis het, sal u eers ander medisynes kry. As u nie goed genoeg reageer nie of hierdie medisynes nie kan verdra nie, kan u STELARA kry om die tekens en simptome van u siekte te verminder.

2. Wat u moet weet voordat u STELARA gebruik

Moenie STELARA gebruik as u:

- **hipersensitief (allergies)** is vir ustekinumab of vir enige van die ander bestanddele van STELARA nie (gelys in Afdeling 6);
- **tuberkulose (TB)** het nie.

Waarskuwings en voorsorgmaatreëls

Sê vir u dokter of verskaffer van gesondheidsorg voordat u ’n inspuiting kry:

Praat met u dokter of apteker voordat u STELARA gebruik. U dokter sal vóór behandeling kyk hoe gesond u is. Sorg dat u vir u dokter sê van enige siekte wat u voor behandeling het. Sê ook vir u dokter as u onlangs naby iemand was wat dalk tuberkulose het. Voordat u STELARA kry, sal u dokter u ondersoek en ’n toets vir tuberkulose doen. As u dokter dink u loop die risiko om tuberkulose te kry, kan u medisynes kry om dit te behandel.

Wees op die uitkyk vir ernstige newe-effekte

STELARA kan ernstige newe-effekte veroorsaak, insluitende allergiese reaksies en infeksies. U moet op die uitkyk wees vir sekere tekens van siekte terwyl u STELARA neem. Sien ‘Ernstige newe-effekte’ in Afdeling 4 vir ’n volledige lys van hierdie newe-effekte.

Neem spesiale sorg met STELARA:

Sê vir u dokter van al u mediese toestande voor elke behandeling, insluitende as u:

- **al ooit ’n allergiese reaksie op STELARA gehad het.** Vra vir u dokter as u nie seker is nie;
- **enige soort infeksie het**, selfs al is dit baie gering, of as u enige tekens van ’n infeksie het. Dit kan koors, moegheid, hoes, griepagtige simptome, diarree, tandprobleme en ’n brandsensasie tydens urinering insluit. Sê ook vir u dokter as u enige oop snytjies of seertjies het, as u ’n infeksie het wat nie weggaan nie of as u ’n geskiedenis het van ’n infeksie wat aanhou terugkom. Dit is belangrik omdat STELARA u vermoë om infeksies te bestry, kan verlaag. Party infeksies kan ernstig raak en tot hospitalisasie lei;
- **enige soort kanker het of gehad het.** Medisynes soos STELARA wat die immuunstelsel se werking verlaag, kan die risiko van kanker verhoog;
- **enige nuwe of veranderende letsels** in gebiede met psoriase of op normale vel het;
- **onlangs ’n entstof ontvang het of geskeduleer is om ’n entstof te ontvang.** Sê vir u dokter as iemand in u huis ’n entstof moet kry. Die virusse in party entstowwe kan versprei na mense met ’n verswakte immuunstelsel en ernstige probleme veroorsaak;
- **inspuitings kry of al ooit gekry het om allergieë te behandel** – dit is nie bekend of STELARA dít kan beïnvloed nie;
- **al ooit ’n allergiese reaksie op lateks of op STELARA inspuiting gehad het** – die voorafgevulde spuit se houer bevat lateksrubber, wat erge allergiese reaksies kan veroorsaak in mense wat sensitief is vir lateks;
- **enige ander behandelingsterapieë ondergaan** – soos immuunonderdrukkende medisyne (’n medisyne wat die werking van u immuunstelsel rem) of fototerapie (wanneer u liggaam met spesifieke ultravioletlig behandel word) terwyl u STELARA gebruik. STELARA het ’n uitwerking op u immuunstelsel en die kombinasie van hierdie terapieë kan die risiko van siektes vergroot wat verband hou met ’n

verswakte immuunstelsel Die kombinasie van hierdie terapieë is egter nie ondersoek nie;

- **swanger is, beplan om swanger te raak of ’n baba borsvoed.** STELARA moet slegs tydens swangerskap gebruik word, as dit nodig is. STELARA kan in baie klein hoeveelhede in u borsmelk beland. Vroue wat hul babas borsvoed. moet met hul dokter praat oor of STELARA gebruik moet word of nie.

U dokter sal u gesondheid vóór behandeling evalueer. Sê vir u dokter van al u mediese toestande.

Kinders en adolessente

STELARA word nie aanbeveel vir kinders met psoriase wat jonger as 6 jaar oud is nie, of vir gebruik in kinders jonger as 18 jaar met psoriatiese artritis, Crohn se siekte of ulseratiewe kolitis nie, aangesien dit nie in hierdie ouderdomsgroep bestudeer is nie.

Ander medisynes, entstowwe en STELARA

Sê altyd vir u verskaffer van gesondheidsorg as u enige ander medisyne neem. (Dit sluit alle aanvullende of tradisionele medisynes in.)

Sê vir u dokter of apteker as u:

- onlangs ’n inenting gehad het of gaan hê. Sekere soorte entstowwe (lewende entstowwe) moet nie vir u gegee word terwyl u STELARA gebruik nie.

As u STELARA gebruik het terwyl u swanger was, moet u vir u baba se dokter sê van u gebruik van STELARA voordat die baba enige entstof ontvang, insluitende lewende entstowwe soos BCG-entstof (gebruik om tuberkulose te voorkom), rotavirus-entstof of enige lewende entstowwe.

STELARA met kos en drinkgoed

STELARA kan met of sonder kos of drinkgoed gebruik word.

Swangerskap en borsvoeding

As u swanger is of u baba borsvoed, dink dat u swanger kan wees of beplan om ’n baba te kry, moet u u dokter, apteker of ander verskaffer van gesondheidsorg asseblief vir advies raadpleeg voordat u hierdie medisyne gebruik.

Die uitwerkings van STELARA in swanger vroue is nie bekend nie. As u swanger is of u baba borsvoed, moet u u dokter, apteker of ander beroepsgesondheidsorgwerker asseblief vir advies raadpleeg voordat u STELARA gebruik.

Bestuur en gebruik van masjiene

Dit is nie bekend of STELARA die vermoë om te bestuur of om masjiene te gebruik, sal beïnvloed nie.

STELARA bevat sukrose

As u dokter vir u gesê het dat u ’n intoleransie vir sekere soorte suiker het, moet u u dokter kontak voordat u STELARA gebruik. STELARA bevat sukrose, wat ’n uitwerking kan hê op die beheer van u bloedsuiker as u diabetes mellitus het.

3. Hoe STELARA gegee sal word

STELARA is bedoel vir gebruik onder die leiding en toesig van ’n dokter wat ondervinding het in die behandeling van toestande waarvoor STELARA bedoel is.

Gebruik hierdie medisyne altyd presies soos u dokter vir u gesê het. Raadpleeg u dokter as u nie seker is nie. Praat met u dokter oor wanneer u u inspuitings en opvolgafsprake sal kry.

U dokter sal vir u sê hoe lank u behandeling met STELARA sal duur. Moenie behandeling vroeg staak nie, aangesien u simptome kan terugkeer. As u die indruk kry dat die

uitwerking van STELARA vir u te sterk of te swak is, moet u vir u dokter of apteker sê.

Hoeveel STELARA word gegee

U dokter sal besluit hoeveel STELARA u moet kry en vir hoe lank.

Volwassenes wat 18 jaar oud of ouer is

Plaakpsoriase en psoriatiese artritis

- Die aanbevole aanvangsdosis is 45 mg STELARA. Pasiënte wat meer as 100 kilogram (kg) weeg, kan met ’n dosis van 90 mg in plaas van 45 mg begin.
- Ná die aanvangsdosis sal u die volgende dosis 4 weke later kry, en dan elke 12 weke. Die volgende dosisse is gewoonlik dieselfde as die aanvangsdosis.

Crohn se siekte of ulseratiewe kolitis

- Tydens behandeling sal u dokter die eerste dosis van ongeveer 6 mg/kg STELARA deur ’n drup in ’n aar in u arm (binneaarse infusie) gee. Ná die aanvangsdosis sal u die volgende dosis van 90 mg STELARA na 8 weke ontvang, dan elke 12 weke daarna deur ’n inspuiting onder die vel (‘onderhuids’).
- In party pasiënte kan 90 mg STELARA elke 8 weke ná die eerste inspuiting onder die vel gegee word. U dokter sal besluit wanneer u u volgende dosis moet kry.

Kinders en adolessente wat 6 jaar oud of ouer is

<u>Psoriase</u>

- Die dokter sal die regte dosis vir u uitwerk, insluitende die hoeveelheid (volume) STELARA wat ingespuit moet word om die regte dosis te gee. Die regte dosis sal afhang van u liggaamsgewig op die tydstip waarop elke dosis gegee word.
- ’n Flessie van 45 mg is beskikbaar vir kinders wat minder as die volle 45 mg dosis moet ontvang.
- As u minder as 60 kg weeg, is die aanbevole dosis 0,75 mg STELARA per kg liggaamsgewig.

- As u 60 kg tot 100 kg weeg, is die aanbevole dosis 45 mg STELARA.
- As u meer as 100 kg weeg, is die aanbevole dosis 90 mg STELARA.
- Ná die aanvangsdosis sal u die volgende dosis 4 weke later kry, en dan elke 12 weke.

Hoe STELARA gegee word

- STELARA word as ’n inspuiting onder die vel (‘onderhuids’) gegee. Aan die begin van u behandeling kan mediese of verpleegpersoneel STELARA inspuit.
- U en u dokter kan egter besluit dat u STELARA self mag inspuit. In hierdie geval sal u opleiding kry oor hoe om STELARA self in te spuit.
- Sien ‘Aanwysings vir toediening’ onderaan hierdie biljet vir aanwysings oor hoe om STELARA in te spuit.

Praat met u dokter as u enige vrae het oor hoe om uself in te spuit.

As u meer STELARA gebruik as wat u moes

As u te veel STELARA gebruik het of gegee is, moet u dadelik met ’n dokter of apteker praat. Hou die buitenste boksie van die medisyne altyd byderhand, selfs al is dit leeg.

As u vergeet om STELARA te gebruik

As u ’n dosis vergeet, moet u u dokter of apteker kontak. Moenie ’n dubbeldosis neem om op te maak vir ’n dosis wat u vergeet het nie.

As u ophou om STELARA te gebruik

Dit is nie gevaarlik om op te hou om STELARA te gebruik nie. As u ophou, kan u simptome egter terugkeer.

Vra vir u dokter of apteker as u enige verdere vrae oor die gebruik van hierdie medisyne het.

4. Moontlike newe-effekte

STELARA kan newe-effekte veroorsaak.

Nie alle newe-effekte wat vir STELARA aangemeld is, is in hierdie biljet vervat nie. Sou u algemene gesondheid versleg of as u enige ongunstige uitwerkings ervaar terwyl u STELARA ontvang, moet u u verskaffer van gesondheidsorg asseblief vir advies kontak.

Sê dadelik vir u dokter of gaan na u naaste hospitaal se ongevalle-afdeling toe as u enige van die volgende newe-effekte ervaar:

- ***Infeksies (insluitende tuberkulose)*** – tekens van infeksie sluit in: koors, moegheid, (aanhoudende) hoes, kortasemigheid, griepagtige simptome, nagsweet, diarree, wonde, tandprobleme en ’n brandsensasie tydens urinering.
- ***Allergiese reaksie*** – tekens van ernstige allergiese reaksies (anafilakse) sluit in: veluitslag; netelroos; swelling van die gesig, lippe, mond of keel wat probleme kan veroorsaak om te sluk of asem te haal; lae bloeddruk wat duiseligheid of lighoofdigheid kan veroorsaak; swelling van die hande, voete of enkels. In seldsame gevalle kan simptome soos ’n hoes, kortasemigheid en koors ook ’n teken van ’n allergiese longreaksie op STELARA wees.

As u ’n ernstige allergiese reaksie het, kan u dokter besluit dat u nie weer STELARA moet gebruik nie.

Hierdie is almal ernstige newe-effekte. U verg dalk dringende mediese hulp.

Ander newe-effekte wat met STELARA waargeneem is, verskyn hieronder. Sê vir u dokter as u enige van hierdie newe-effekte ervaar.

Newe-effekte wat gereeld aangemeld is:

- Diarree
- Moegheid

- Duiseligheid
- Hoofpyn
- Gejeuk
- Rug- of spierpyn
- Keelseer
- Rooiheid en pyn waar die inspuiting gegee is
- Naarheid
- Gewrigspyn
- Braking
- Sinusinfeksie.

Newe-effekte wat minder gereeld aangemeld is:

- Depressie
- Verstopte of toe neus
- Ontsteking van weefsel onder die vel (‘sellulitis’) wat as warmte, swelling, rooiheid en pyn van die vel presenteer
- Pyn, swelling, gejeuk, hardheid, bloeding, kneusing en irritasie by die inspuitplek
- Gordelroos (’n soort pynlike veluitslag met blasies)
- Pustulêre psoriase (’n verandering in psoriase waar rooiheid en nuwe klein, geel of wit velblasies vorm, wat soms met koors gepaard gaan)
- ’n Toename in rooiheid en afdopping van vel oor ’n groter gebied van die liggaam, wat jeukerig of pynlik kan wees (eksfoliatiewe dermatitis)
- Afdopping van die vel (velafdopping)
- Swaminfeksie (sproei) van die vulva en vagina
- Aknee
- Verlies aan krag, swakheid of gebrek aan energie (astenie)
- Tandinfeksies
- Ontsteking van klein bloedvate, wat kan lei tot ’n veluitslag met klein rooi of pers

knoppies, koors of gewrigspyn (vaskulitis).

As u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, moet u asseblief vir u dokter of apteker sê.

Aanmelding van newe-effekte

As u newe-effekte kry, moet u met u dokter, apteker of verpleegkundige praat. U kan newe-effekte ook by SAROG aanmeld aan die hand van die **"*6.04 Adverse Drug Reaction Reporting Form*"** wat aanlyn onder SAROG se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van STELARA te voorsien.

5. Hoe om STELARA te berg

Bêre alle medisyne buite die bereik van kinders.

Bêre in 'n yskas (2 °C–8 °C). STELARA moenie bevries word nie.

STELARA moet nie gebruik word as u weet, of dink, dat dit dalk aan uiterste temperature blootgestel is nie (soos dat dit per ongeluk gevries of warm geword het).

Hou die produk in die oorspronklike buitenste boksie om die oplossing teen lig te beskerm.

Flessies of voorafgevulde spuite met STELARA moet nie geskud word nie. As dit langdurig en goed geskud word, kan die produk beskadig. Moenie die produk gebruik as dit goed geskud is nie.

Moenie STELARA ná die vervaldatum (na "VERV.") wat op die etiket en boksie verskyn, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Moenie STELARA gebruik as die seël gebreek is nie.

Die oplossing is helder tot effens wisselkleurig, kleurloos tot liggeel en kan ’n paar deurskynende of wit proteïendeeltjies bevat. Hierdie voorkoms is nie ongewoon vir oplossings wat proteïen bevat nie. Moenie STELARA gebruik as die vloeistof verkleur, troebel is of as u ander vreemde deeltjies daarin kan sien dryf nie.

Moenie STELARA met ander vloeistowwe vir inspuiting meng nie.

STELARA is slegs vir eenmalige gebruik. Enige ongebruikte produk wat in die flessie en die voorafgevulde spuit oorbly, moet weggegooi word.

Besorg alle ongebruikte medisyne terug aan u apteker. Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat STELARA bevat

- Die aktiewe stof is ustekinumab. Elke flessie of voorafgevulde spuit bevat 45 mg ustekinumab in 0,5 ml of 90 mg ustekinumab in 1 ml.
- Die ander bestanddele is L-histidien, L-histidien monohidrochloriedmonohidraat, polisorbaat 80, sukrose en water vir inspuiting.
- Bevat suiker (sukrose).
- STELARA 45 mg onderhuidse dosis bevat 38 mg sukrose.
- STELARA 90 mg onderhuidse dosis bevat 76 mg sukrose.

Hoe STELARA lyk en inhoud van die pakkie

STELARA is ’n helder tot effens wisselkleurige (met ’n pêrelagtige skynsel), kleurlose tot liggeel oplossing vir inspuiting. Die oplossing kan ’n paar klein deurskynende of wit deeltjies proteïen bevat.

Dit word verskaf as ’n kartonpakkie wat 1 enkeldosis, 2 ml glasflessie bevat.

Alternatiewelik word dit voorsien as ’n kartonboksie wat 1 enkeldosis, 1 ml voorafgevulde

glasspuit bevat.

Elke flessie of voorafgevulde spuit bevat 45 mg ustekinumab in 0,5 ml of 90 mg ustekinumab in 1 ml oplossing vir inspuiting.

Houer van Registrasiesertifikaat

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Hierdie biljet se jongste bywerking was op

Datum van registrasie van STELARA 45 mg en 90 mg: 27 Julie 2012

Datum van bywerking van teks: 24 Augustus 2023

Registrasienommers

STELARA 45 mg: 43/30.1/0727

STELARA 90 mg: 43/30.1/0728

Toegang tot die ooreenstemmende Professionele Inligting:

Ingesluit in die boksie wat saam met hierdie pasiëntinligtingsbiljet kom.

VERDERE INLIGTING

AANWYSINGS VIR TOEDIENING

Aan die begin van u terapie kan STELARA deur mediese of verpleegpersoneel ingespuit word. U dokter kan egter besluit dat u STELARA self mag inspuit. In hierdie geval sal u opleiding ontvang oor hoe om STELARA in te spuit. Bel u dokter as u enige vrae het oor hoe om uself in te spuit.

STELARA moet nie met ander vloeistowwe vir inspuiting gemeng word nie.

AANWYSINGS VIR DIE INSPUIT VAN STELARA UIT 'N FLESSIE:

Moenie flessies met STELARA skud nie. As dit langdurig en goed geskud word, kan die produk beskadig. Moenie die produk gebruik as dit goed geskud is nie.

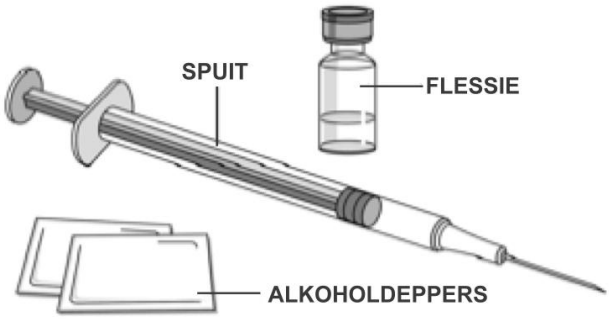
1. Gaan die flessies na en kry alle materiaal bymekaar:

Haal die flessie uit die yskas. Laat die flessie vir ongeveer 'n halfuur staan. Dit sal maak dat die vloeistof 'n gemaklike temperatuur vir inspuiting bereik (kamertemperatuur).

As u dosis 45 mg is, sal u een flessie van 45 mg STELARA ontvang. As u dosis 90 mg is, sal u hetsy een flessie van 90 mg STELARA of twee flessies van 45 mg STELARA ontvang en u sal uself twee inspuitings moet gee. Kies twee verskillende plekke vir hierdie inspuitings (byvoorbeeld een inspuiting in die regterbobeen en die ander inspuiting in die linkerbobeen), en gee die inspuitings direk na mekaar. Gebruik 'n nuwe naald en spuit vir elke inspuiting.

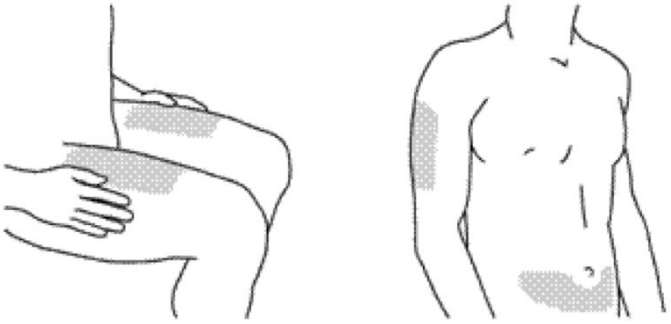
- Gaan die flessie(s) na om seker te maak dat dit die regte produk is (m.a.w. aantal flessies en sterkte is korrek) en dat dit nie ná die vervaldatum is nie.
- Maak seker die flessie is nie beskadig nie, dat die seël nie gebreek is nie en dat die vloeistof helder tot effens wisselkleurig en kleurloos tot effens geel is. MOENIE gebruik as dit bevrore, verkleur of troebel is of groot deeltjies bevat nie.
- Was u hande deeglik met seep en warm water.

- Kry alles wat u nodig het, soos ’n spuit, naald en antiseptiese deppers, bymekaar en lê dit uit op ’n skoon oppervlak.



2. Kies en berei die inspuitplek voor:

- Kies ’n inspuitplek. STELARA word deur inspuiting onder die vel (onderhuids) gegee. Goeie plekke vir die inspuiting is die bokant van die bobeen of om die maag (buik), minstens 5 cm weg van die naeltjie af. Indien moontlik, moet gebiede van die vel vermy word wat reeds simptome van psoriase toon. As iemand u sal help om die inspuiting te gee, kan hy/sy ook die bo-arms of boude as inspuitplek kies.

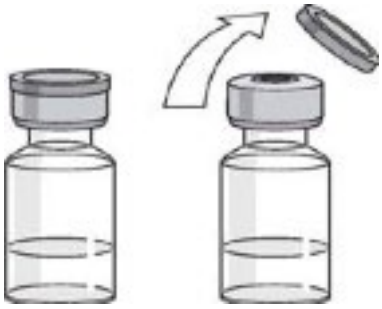


***Gebiede in grys is aanbevole inspuitplekke.**

- Voorbereiding van die inspuitplek. Vee die inspuitplek met ’n alkoholdepper. **MOENIE** weer aan hierdie gebied raak voordat u die inspuiting gee nie.

3. Voorbereiding van die dosis:

- Haal die doppie van die flessie se bokant af, maar moenie die prop afhaal nie.



- Maak die prop skoon met ’n antiseptiese depper.
- Haal die naaldbedekking af. Moenie aan die naald raak of toelaat dat die naald aan enigiets raak nie.
- Sit die flessie op ’n plat oppervlak en druk die spuitnaald deur die rubberprop.
- Draai die flessie en die spuit onderstebo. Trek aan die spuit se suier om die spuit met die hoeveelheid vloeistof te vul wat deur u dokter voorgeskryf is (0,5 ml–1 ml). Dit is belangrik dat die naald altyd in die vloeistof is om te voorkom dat lugborrels in die spuit vorm.



- Trek die naald uit die flessie. Hou die spuit met die naald wat boontoe wys om te kyk of daar enige lugborrels in is. As daar lugborrels is, moet u die kant liggies tik totdat die lugborrels na die bokant van die spuit toe beweeg en die suier dan druk totdat al die lug (maar niks van die vloeistof nie) verwyder is. Moenie die spuit neerlê of toelaat dat die naald aan enigiets raak nie.



4. Spuit die dosis in:

- Knyp die skoongemaakte vel liggies tussen u duim en wysvinger vas. Moenie dit druk nie.
- Druk die spuitnaald in die geknypte vel.
- Druk die suier al die pad met u duim om al die vloeistof in te spuit. Druk dit stadig en geleidelik in, met die vel steeds liggies vasgeknyp.



- Wanneer die suier al die pad ingedruk is, moet die naald uitgetrek en die vel gelos word.
- Gooi u gebruikte spuit in ’n veilige houer en gooi u flessie weg. Sien afdeling 5 “Hoe om STELARA te berg”.

5. Ná die inspuiting:

- Druk ’n antiseptiese lappie vir ’n paar sekondes ná die inspuiting oor die inspuitplek.
- Daar kan dalk ’n klein bietjie bloed of vloeistof by die inspuitplek wees. Dit is normaal.
- U kan ’n watteboltjie of gaas oor die inspuitplek druk en dit vir 10 sekondes daar hou.
- Moenie die vel by die inspuitplek vryf nie. Indien nodig, kan u die inspuitplek met ’n klein kleefverband toeplak.

6. Wegdoening:

- Gebruikte spuite en naalde moet in ’n prikbestande houer, soos ’n houer vir skerp voorwerpe, geplaas word. Vir u veiligheid en gesondheid, en dié van ander mense, moet naalde en spuite nooit hergebruik word nie. Gooi u houer vir skerp voorwerpe volgens u plaaslike regulasies weg.
- Leë flessies, antiseptiese lappies en ander voorraad kan in u vullis weggegooi word.

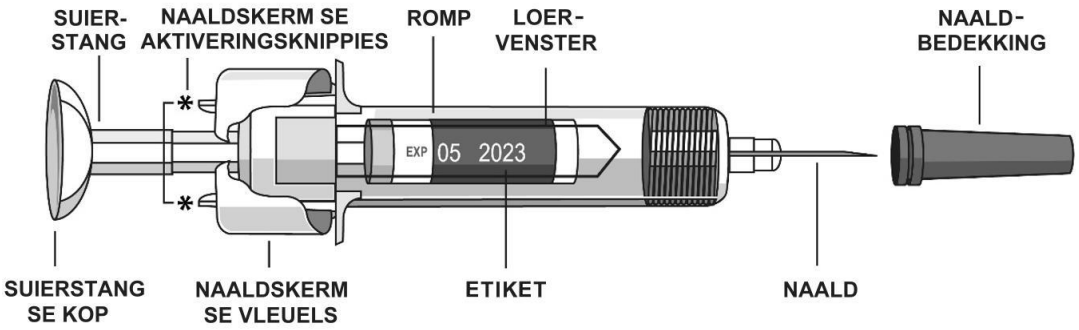
AANWYSINGS VIR DIE INSPUIT VAN STELARA MET GEBRUIK VAN ’N VOORAFGEVULDE SPUIT

U verskaffer van gesondheidsorg sal u aan die begin van behandeling met u eerste inspuiting help. U en u dokter kan egter besluit dat u STELARA self mag inspuit. As dit gebeur, sal u opleiding kry oor hoe om STELARA in te spuit. Praat met u dokter as u enige vrae het oor hoe om uself in te spuit.

- Moenie STELARA met ander vloeistowwe vir inspuiting meng nie.
- Voorafgevulde spuite met STELARA moet nie geskud word nie. Dit is omdat ’n goeie skud die medisyne kan beskadig. Moenie die medisyne gebruik as dit goed geskud is nie.

Om die risiko van onopsetlike naaldprikke aan gebruikers te verminder, is elke voorafgevulde spuit toegerus met ’n naaldskerm wat outomaties geaktiveer word om die naald te bedek nadat die spuit se inhoud volledig toegedien is.

1. Voorbereiding vir gebruik van voorafgevulde spuit

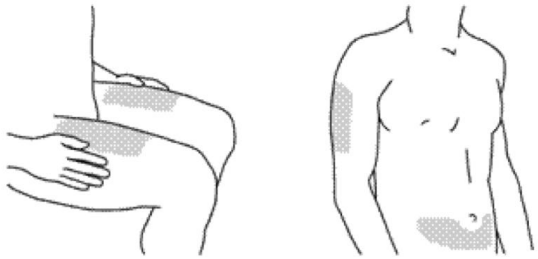


- Haal die voorafgevulde spuit(e) uit die yskas. Laat die voorafgevulde spuit vir ongeveer ’n halfuur buite die boksie staan. Dit sal maak dat die vloeistof ’n gemaklike temperatuur vir inspuiting bereik (kamertemperatuur). Moenie die spuit se naaldbedekking afhaal terwyl dit gelaat word om kamertemperatuur te bereik nie.
- Gaan die verpakking na om seker te maak dat dit die regte dosis is (d.w.s. dat die aantal voorafgevulde spuite en sterkte korrek is).
    - As u dosis 45 mg is, sal u een voorafgevulde spuit met 45 mg STELARA kry.
    - As u dosis 90 mg is, sal u twee voorafgevulde spuite met 45 mg STELARA of

een voorafgevulde spuit met 90 mg STELARA kry en u sal uself twee inspuitings moet gee. Kies twee verskillende plekke vir hierdie inspuitings (bv. een inspuiting in die regterbobeen en die ander inspuiting in die linkerbobeen), en gee die inspuitings direk na mekaar.

- Maak die boksie oop en haal die voorafgevulde spuit uit. Gaan die vervaldatum op die voorafgevulde spuit en op die boksie se etiket na. Moenie dit gebruik as dit ná die vervaldatum is nie.
- Kry die bykomende voorraad bymekaar wat u vir u inspuiting benodig. Dit sluit ’n antiseptiese lappie, ’n watteboletjie of gaas, en ’n houer vir skerp voorwerpe vir die wegdoening van die spuit in.
- Hou die voorafgevulde spuit met die bedekte naald wat boontoe wys.
- Moenie aan die suier se kop, stang, naaldskerm se vleuels of naaldbedekking vashou nie.
- Maak seker dat die spuit nie beskadig is nie. Kyk na die oplossing of vloeistof in die spuit om seker te maak dat dit helder tot effens wisselkleurig en kleurloos tot effens geel is. **MOENIE** gebruik as dit bevrore, verkleur, troebel is of groot deeltjies bevat nie en kontak u verskaffer van gesondheidsorg vir hulp.
- **MOENIE** die voorafgevulde spuit se naaldbedekking afhaal totdat u opdrag kry om dit te doen nie.
- **MOENIE** die suier se kop enige tyd terugtrek nie.
- **MOENIE** aan die naaldskerm se aktiveringsknippes raak (soos aangedui deur sterretjies * in die figuur hierbo) nie, om te voorkom dat die naaldskerm die naald voortydig bedek.

2. Kies en berei die inspuitplek voor

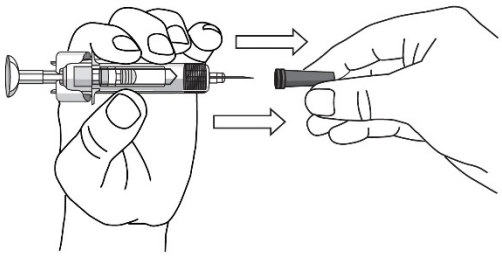


*Gebiede in grys is aanbevole inspuitplekke.

- STELARA word deur inspuiting onder die vel (onderhuids) gegee.
- Goeie plekke is die bokant van die bobeen en om die maag (buik), maar ongeveer 5 cm weg van die naeltjie af. Indien moontlik, moet vel met psoriase vermy word. As u versorger die inspuiting vir u gee, kan hy of sy ook die bo-arms gebruik.
- Was u hande deeglik met seep en warm water. Vee die inspuitplek met ’n antiseptiese lappie. MOENIE weer aan hierdie gebied raak voordat u die inspuiting gee nie.

3. Haal die naaldbedekking af.

- Die naaldbedekking moet **nie** afgehaal word totdat u gereed is om die dosis in te spuit nie.
- Tel die voorafgevulde spuit op, hou die spuit se romp met een hand vas.
- Trek die naaldbedekking reguit af en gooi dit weg. Moenie aan die suier raak terwyl u dit doen nie.

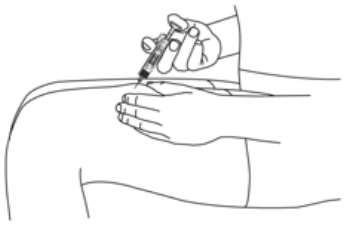


- U sal dalk ’n lugborreltjie in die voorafgevulde spuit sien. U hoef die lugborreltjie nie te verwyder nie. U kan ook ’n druppel vloeistof op die naald se punt sien – dit is normaal en hoef nie verwyder te word nie. Moenie aan die naald raak of dit met enige oppervlak in aanraking laat kom nie. **Let wel:** Die naaldbedekking moet **NIE** afgehaal word totdat u gereed is om die dosis in te spuit nie.

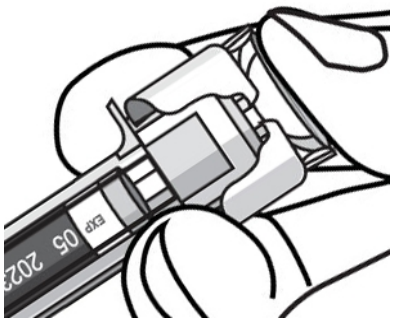
- Moenie die voorafgevulde spuit gebruik as dit laat val word sonder dat die naaldbedekking in plek is nie. As u die spuit laat val sonder dat die naaldbedekking in plek is, moet u u verskaffer van gesondheidsorg asseblief vir hulp kontak. Spuit die dosis onverwyld in nadat die naaldbedekking afgehaal is.

4. Spuit die dosis in

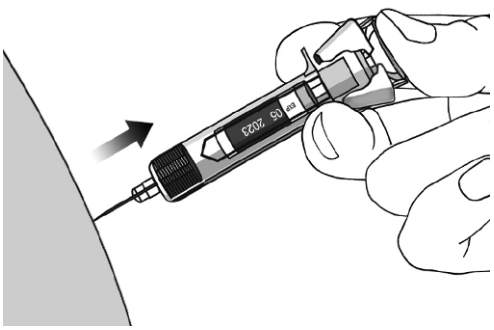
- Hou die voorafgevulde spuit met een hand tussen die middel- en wysvinger en plaas die duim bo-op die suier se kop en gebruik die ander hand om die skoongemaakte vel liggies tussen u duim en wysvinger vas te knyp. Moenie dit styf druk nie.
- Moenie die suier enige tyd terugtrek nie.
- In ’n enkele en vinnige beweging, word die naald al die pad deur die vel gesteek.



- Spuit al die medikasie in deur die suier in te druk totdat die suier se kop heeltemal tussen die naaldskerm se vleuels is.



- Wanneer die suier al die pad ingedruk is, moet u die druk op die suier se kop volhou, die naald uittrek en die vel laat los.



- Haal u duim stadig van die suier se kop af en laat die leë spuit opwaarts beweeg totdat die hele naald deur die naaldskerm bedek is, soos hieronder aangedui.



5. Ná die inspuiting

- Druk ’n antiseptiese lappie vir ’n paar sekondes ná die inspuiting oor die inspuitplek.
- Daar kan dalk ’n klein bietjie bloed of vloeistof by die inspuitplek wees. Dit is normaal.
- U kan ’n wattebolletjie of gaas oor die inspuitplek druk en dit vir 10 sekondes daar hou.
- Moenie die vel by die inspuitplek vryf nie. Indien nodig, kan u die inspuitplek met ’n klein kleefverband toeplak.

6. Wegdoening

- Gebruikte spuite moet in ’n prikbestande houer, soos ’n houer vir skerp voorwerpe, geplaas word (sien hieronder). Vir u veiligheid en gesondheid, en dié van ander mense, moet ’n spuit nooit hergebruik word nie. Gooi u houer vir skerp voorwerpe volgens u plaaslike regulasies weg.
- Antiseptiese lappies en ander voorraad kan in u vullis weggegooi word.

