Applicant: **JANSSEN PHARMACEUTICA (PTY) LTD**
Product Proprietary Name: **STELARA® 130 mg (51/30.1/0851)**
Dosage form and strength: Concentrate for solution for infusion; 130 mg ustekinumab in 26 mL (5 mg/mL)
Approval date : September 2023
Reference number: RA/2022/08/334cp
Submission type: eCTD seq 0004: Safety updates: hypersensitivity vasculitis as ADR & live vaccine in infants & lactation

Professional Information (PI)

SCHEDULING STATUS

Schedule 4

1. NAME OF THE MEDICINE

STELARA® 130 mg concentrate for solution for infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 130 mg ustekinumab in 26 mL (5 mg/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 130 mg intravenous loading dose contains 2 210 mg sucrose per vial.

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion.

The solution is clear and colourless to light yellow.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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 concentrate for solution for infusion is intended for use under the guidance and supervision of medical practitioners experienced in the diagnosis and treatment of Crohn's disease or ulcerative colitis. STELARA concentrate for solution for infusion should only be used for the intravenous induction dose.

Posology

Crohn's Disease and Ulcerative Colitis

STELARA treatment is to be initiated with a single intravenous dose based on body weight. The infusion solution is to be composed of the number of vials of STELARA 130 mg as specified in Table 1 (see section 6.6 for preparation).

Table 1 Initial intravenous dosing of STELARA

Body weight of patient at	**Recommended dose** [a]	**Number of 130 mg**

the time of dosing		**STELARA vials**
≤ 55 kg	260 mg	2
> 55 kg to ≤ 85 kg	390 mg	3
> 85 kg	520 mg	4

[a] Approximately 6 mg/kg

The first subcutaneous dose should be given at week 8 following the intravenous dose. For the posology of the subsequent subcutaneous dosing regimen, see section 4.2 of the STELARA solution for injection (vial) and solution for injection in pre-filled syringe Professional Information.

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 for the treatment of Crohn's disease or ulcerative colitis in children less than 18 years have not yet been established. No data are available.

Method of administration

STELARA 130 mg is for intravenous use only. It should be administered over at least one hour.

For instructions on dilution of the medicinal product before administration, 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).

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 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 2 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 2: 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 and infusion reactions

In Crohn's disease and ulcerative colitis intravenous induction studies, no events of anaphylaxis or other serious infusion reactions were reported following the single intravenous dose. In these studies, 2,2 % of 785 placebo treated patients and 1,9 % of 790 patients treated with the recommended dose of STELARA reported adverse events occurring during or within an hour of the infusion.

Postmarketing experience

Table 3: 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

Following the recommended intravenous induction dose, median peak serum ustekinumab concentration, observed 1 hour after the infusion, was 126,1 µg/mL in patients with Crohn's disease and 127,0 µg/mL in patients with ulcerative colitis.

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.

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

EDTA disodium salt dihydrate

L-histidine

L-histidine monohydrochloride monohydrate

L-methionine

Polysorbate 80

Sucrose

Water for injection

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines. STELARA should only be diluted with sodium chloride 9 mg/mL (0,9 %) solution. STELARA should not be administered concomitantly in the same intravenous line with other medicinal products.

6.3 Shelf life

3 years.

Do not freeze.

Chemical and physical in-use stability has been demonstrated for 4 hours at 15-25 °C.

From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of user.

6.4 Special precautions for storage

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

Keep the vial in the outer carton until time of use in order to protect from light.

Do not freeze. Do not shake.

For storage conditions after dilution of the medicinal product, see section 6.3

6.5 Nature and contents of container

26 mL solution in a type I glass 30 mL vial closed with a coated butyl rubber stopper.

STELARA is available in a 1 vial pack.

6.6 Special precautions for disposal and other handling

The solution in the STELARA vial should not be shaken. The solution should be visually inspected for particulate matter or discolouration prior to administration. The solution is clear, colourless to light yellow. The medicine should not be used if the solution is discoloured or cloudy, or if foreign particulate matter is present.

Dilution

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

1. Calculate the dose and the number of STELARA vials needed based on patient's body weight (see section 4.2, Table 1). Each 26 mL vial of STELARA contains 130 mg of ustekinumab. Only use complete vials of STELARA.
2. Withdraw and discard a volume of the sodium chloride 9 mg/mL (0,9%) solution from the 250 mL infusion bag equal to the volume of STELARA to be added. (discard 26 mL sodium chloride for each vial of STELARA needed, for 2 vials- discard 52 mL, for 3 vials- discard 78 mL, for 4 vials- discard 104 mL)

3. Withdraw 26 mL of STELARA from each vial needed and add it to the 250 mL infusion bag. The final volume in the infusion bag should be 250 mL. Gently mix.
4. Visually inspect the diluted solution before administration. Do not use if visibly opaque particles, discolouration or foreign particles are observed.
5. Administer the diluted solution over a period of at least one hour. Once diluted, the infusion should be completed within four hours of the dilution in the infusion bag.
6. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 micrometer).
7. Do not infuse STELARA concomitantly in the same intravenous line with other medicines.
8. Each vial is for single use only and any unused medicine should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER(S)

51/30.1/0851

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9 December 2019

10. DATE OF REVISION OF THE TEXT

30 August 2023

Patient Information Leaflet (PIL)

SCHEDULING STATUS

Schedule 4

STELARA® 130 mg concentrate for solution for infusion

Ustekinumab

Contains sugar (sucrose).

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

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:

- Moderate to severe Crohn's disease - in adults
- Moderate to severe ulcerative colitis - in adults

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 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 under 18 years of age with 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 130 mg is for intravenous infusion after dilution. It will be given to you by a person who is qualified to do so.

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.

STELARA is intended for use under the guidance and supervision of a doctor experienced in the diagnosis and treatment of Crohn's disease or ulcerative colitis.

STELARA 130 mg concentrate for solution for infusion will be given to you by your doctor, through a drip in the vein of your arm (intravenous infusion) over at least one hour. Talk to your doctor about when you will have your injections and follow-up appointments.

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

- The doctor will work out the recommended intravenous infusion dose for you based on your body weight.

Your body weight	Dose
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

- After the starting intravenous dose, you will have the next dose of 90 mg STELARA by an injection under your skin (subcutaneous injection) 8 weeks later, and then every 12 weeks thereafter.

How STELARA is given

- The first dose of STELARA for treatment of Crohn's disease or ulcerative colitis is given by a doctor as a drip in the vein of an arm (intravenous infusion).

Talk to your doctor if you have any questions about receiving STELARA.

If you use more STELARA than you should

Since a health care provider will administer STELARA, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use STELARA

If you forget or miss the appointment for receiving the dose, contact your doctor to reschedule your appointment. Since a health care provider will administer STELARA, it is unlikely that the dose will be missed.

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.

STELARA 130 mg concentrate for solution for infusion is given in a hospital or clinic and patients should not need to store or handle it.

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. 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 diluted infusion solution or unused product remaining in the vial and the syringe should be thrown away in accordance with local requirements.

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 contains 130 mg of ustekinumab in 26 mL.
- The other ingredients are EDTA disodium salt dihydrate, L-histidine, L-histidine monohydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for injection.
- Contains sugar (sucrose). STELARA 130 mg intravenous loading dose contains 2 210 mg sucrose per vial.

What STELARA looks like and contents of the pack

STELARA is a clear, colourless to light yellow concentrate for solution for infusion. It is

supplied as a carton pack containing 1 single-dose, glass Type I 30 mL vial closed with a coated butyl rubber stopper. Each vial contains 130 mg ustekinumab in 26 mL of concentrate for solution for infusion.

Holder of Certificate of Registration

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Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.

Pasiëntinligtingsbiljet (PIB)

SKEDULERINGSTATUS
Skedule 4

STELARA® 130 mg konsentraat vir oplossing vir infusie

Ustekinumab

Bevat suiker (sukrose).

STELARA 130 mg binnespierse laaidosis bevat 2 210 mg sukrose per flessie.

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:

- Matige tot erge Crohn se siekte – in volwassenes
- Matige tot erge ulseratiewe kolitis – in volwassenes.

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;
- **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 jonger as 18 jaar met 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 gegee word terwyl STELARA gebruik word 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 130 mg is vir binneaarse infusie nadat dit verdun is. Iemand wat gekwalifiseer is om dit te doen, sal dit vir u gee.

U dokter sal vir u sê hoe lank 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.

STELARA is bedoel vir gebruik onder die leiding en toesig van ’n dokter wat ervare is in die diagnose en behandeling van Crohn se siekte of ulseratiewe kolitis.

U dokter sal STELARA 130 mg konsentraat vir oplossing vir infusie deur ’n drup in die aar van u arm (binneaarse infusie) oor minstens een uur gee. Praat met u dokter oor wanneer u u inspuitings sal kry en opvolgafsprake sal hê.

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

- Die dokter sal die aanbevole dosis binneaarse infusie op grond van u liggaamsgewig bereken.

U liggaamsgewig	Dosis
≤ 55 kg	260 mg
> 55 kg tot ≤ 85 kg	390 mg
> 85 kg	520 mg

- Ná die eerste binneaarse dosis sal u die volgende dosis van 90 mg STELARA 8 weke later deur ’n inspuiting onder u vel (onderhuidse inspuiting) kry, en dan elke 12 weke daarna.

Hoe STELARA gegee word

- Die eerste dosis STELARA vir die behandeling van Crohn se siekte of ulseratiewe kolitis word deur ’n dokter as ’n drup in die aar van ’n arm gegee (binneaarse infusie).

Praat met u dokter as u enige vrae oor die ontvangs van STELARA het.

As u meer STELARA gebruik as wat u moes

Aangesien ’n verskaffer van gesondheidsorg STELARA sal toedien, sal hy/sy die dosering beheer. In die geval van oordosering, sal u dokter die oordosering egter hanteer.

As u vergeet om STELARA te gebruik

As u die afspraak vir die ontvangs van die dosis vergeet of misloop, moet u u dokter kontak om u afspraak te herskeduleer. Aangesien ’n verskaffer van gesondheidsorg STELARA sal toedien, is dit onwaarskynlik dat die dosis misgeloop sal word.

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.

STELARA 130 mg konsentraat vir oplossing vir infusie word in ’n hospitaal of kliniek gegee en pasiënte behoort dit nie te hoef berg of te hanteer nie.

Berg in ’n yskas (2 °C tot 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.

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.

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 verdunde infusie-oplossing of ongebruikte produk wat oorbly in die flessie, asook die spuit, moet in ooreenstemming met plaaslike vereistes 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 bevat 130 mg ustekinumab in 26 ml.
- Die ander bestanddele is EDTA dinatriumsoutdihidraat, L-histidien, L-histidienmonohidrochloriedmonohidraat, L-metionien, polisorbaat 80, sukrose en water vir inspuiting.
- Bevat suiker (sukrose). STELARA 130 mg binnespierse laaidosis bevat 2 210 mg sukrose per flessie.

Hoe STELARA lyk en inhoud van die pakkie

STELARA is ’n helder, kleurlose tot liggeel konsentraat vir oplossing vir infusie. Dit word verskaf as ’n kartonpakkie wat 1 enkeldosis, 30 ml Tipe I-glasflessie bevat wat toe is met ’n prop wat met butielrupper bedek is. Elke flessie bevat 130 mg ustekinumab in 26 ml konsentraat vir oplossing vir infusie.

Houer van Registrasiesertifikaat

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Hierdie biljet se jongste bywerking was op

Datum van registrasie: 9 Desember 2019

Datum van bywerking van teks: 30 Augustus 2023

Registrasienommer

51/30.1/0851

Toegang tot die ooreenstemmende Professionele Inligting:

Ingesluit in die boksie wat saam met hierdie pasiëntinligtingsbiljet kom.