Approved 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.

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.

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 taking 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.

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

JANSSEN PHARMACEUTICA (PTY) LTD

(Reg. No. 1980/011122/07)

2 Medical Road, Halfway House

Midrand, 1685

Tel: +27 (0)11 518 7000

MedInfoZA@its.jnj.com

This leaflet was last revised in

Date of registration: 9 December 2019

Date of revision of text: 13 December 2021

Registration number

51/30.1/0851

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.