

6. FURTHER INFORMATION

What STELARA contains

- The active substance is ustekinumab. Each vial contains 45 mg ustekinumab (45 mg in 0.5 ml).
- The other ingredients are sucrose, L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 and water for injections.

What STELARA looks like and contents of the pack

STELARA is a clear to slightly opalescent, 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. Each vial contains 45 mg ustekinumab in 0.5 ml of solution for injection.

Marketing Authorisation Holder

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INSTRUCTIONS FOR ADMINISTRATION

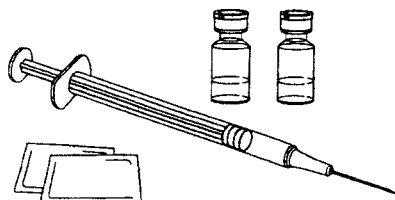
At the start of treatment, medical or nursing staff assists you with your first injection. However, you and your doctor may decide that you may inject STELARA yourself. If this happens, you will get training on how to inject STELARA. Talk to your doctor if you have any questions about giving yourself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

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

1. Check the number of vials and prepare the materials:

Take the vial(s) out of the refrigerator and check the vial(s) to make sure

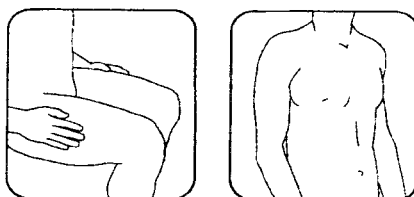
- the number of vials and strength is correct
 - If your dose is 45 mg you will get one 45 mg vial of STELARA
 - If your dose is 90 mg you will get two 45 mg vials of STELARA and you will need to give yourself two injections. Choose two different sites for these injections (e.g. one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other. Use a new needle and syringe for each injection.
 - it is the right medicine
 - it has not passed its expiry date
 - the vial is not damaged and the seal is not broken
 - the solution is not discoloured, cloudy or contains any foreign particles
 - the solution is not frozen.
-
- Let the vial stand for about half an hour. This will let the liquid come to a comfortable temperature for injection.
 - Wash your hands very well with soap and warm water
 - Get everything together that you need and lay out on a clean surface. This includes a syringe, needle and antiseptic swabs.



2. Choose and prepare the injection site:

Choose an injection site

- STELARA is given by injection under your skin (subcutaneously)
- Good places for the injection are the upper thigh or around the belly (abdomen) at least 5 cm away from the navel (belly button)
- If possible, do not use areas of skin that show signs of psoriasis
- If someone will assist in giving you the injection, then he or she may also choose the upper arms or buttocks as an injection site.

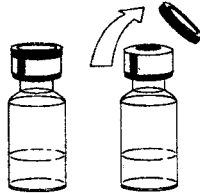


Prepare the injection site

- Wipe the injection site on the skin with an alcohol swab
- **Do not touch this area again before giving the injection.**

3. Prepare the dose:

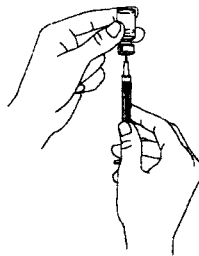
- Take the cap off the top of the vial



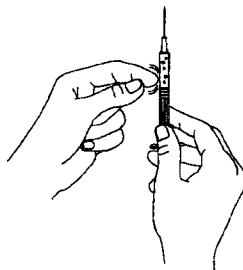
- Do not remove the stopper
- Clean the stopper with an antiseptic swab
- Put the vial on a flat surface.

Remove the needle cover

- Do not touch the needle or let the needle touch anything
- Push the 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 in the vial
- It is important that the needle is always in the liquid. This stops 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



- Then 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. Inject the dose:

- Gently pinch the cleaned skin between your thumb and index finger. Do not squeeze it tightly
- Push the 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
- Press an antiseptic swab over the injection site for a few seconds after the injection.

5. Disposal:

- Used syringes and needles should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your local regulations
- Empty vials, antiseptic wipes, and other supplies can be disposed in your garbage.

PACKAGE LEAFLET: INFORMATION FOR THE USER

STELARA 90 mg solution for injection Ustekinumab

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What STELARA is and what it is used for
2. Before you use STELARA
3. How to use STELARA
4. Possible side effects
7. How to store STELARA
8. Further information

1. WHAT STELARA IS AND WHAT IT IS USED FOR

STELARA belongs to a group of medicines called immunosuppressants (medicines that inhibit your immune system). STELARA contains the active substance ustekinumab, a monoclonal antibody.

STELARA is used to treat moderate to severe plaque psoriasis in patients who cannot use or did not respond to other medicines and phototherapy. This disease causes inflammation of skin and nails. STELARA will reduce the inflammation and other signs of the disease.

2. BEFORE YOU USE STELARA

Do not use STELARA

- If you are allergic (hypersensitive) to ustekinumab or to any of the other ingredients of STELARA (listed in section 6 'What STELARA contains').
- If you have an active infection which your doctor considers important (see also below 'Take special care with STELARA').

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using STELARA.

Take special care with STELARA

Your doctor will assess your health before treatment. Make sure you tell your doctor about any illness you have. Check with your doctor before using STELARA if you have:

- **Infections**
 - **You must tell your doctor if you have any kind of infection**
STELARA may make you less able to fight infections. Some infections could also become serious.
 - Tell your doctor if you have any signs of infection, even if it is very minor. Signs may include fever, feeling tired, cough, flu-like symptoms, diarrhoea, dental problems and burning when urinating. If you are not sure, talk to your doctor straight away
 - It is particularly important to tell your doctor if you have an infection that will not go away or keeps coming back
 - Tell your doctor if you have any open cuts or sores – they might get infected.

 - **Tuberculosis (TB)**
 - Tell your doctor if you have had tuberculosis. Also tell him or her if you have recently been near anyone who might have tuberculosis
 - Your doctor will examine you for tuberculosis and perform a test to see if you have tuberculosis, before you are given STELARA
 - If your doctor thinks that you are at risk of tuberculosis, you may be given medicines for tuberculosis. This will be before you begin treatment with STELARA, and during treatment with STELARA.

- **Cancer.** Immunosuppressants like STELARA decrease the activity of the immune system. This may increase the risk of cancer. Tell your doctor if you have ever had any type of cancer.

- **Vaccinations.** Tell your doctor if you have recently had or are going to have a vaccine.

- **Other therapies for psoriasis.** Tell your doctor if you are receiving any other immunosuppressant or phototherapy (when your body is treated with specific ultraviolet (UV) light) while using STELARA, which may also decrease the activity of your immune system. The combination of these therapies has not been investigated and it may increase the risk of diseases related to a weakened immune system.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using STELARA.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not be given certain types of vaccines while on treatment with STELARA.

Pregnancy and breast-feeding

Talk to your doctor before using STELARA:

- If you are pregnant or are planning to become pregnant while using STELARA. The effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using STELARA and for at least 15 weeks after the last STELARA treatment.
- If you are breast-feeding or if you plan to breast-feed while using STELARA. Your doctor will decide whether you should use this medicine.

Driving and using machines

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

3. HOW TO USE STELARA

Always use STELARA exactly as your doctor has told you. You should check with your doctor if you are not sure. Make sure you discuss with your doctor when you will have your injections and your follow-up appointments.

How much STELARA is given

- Your doctor will decide how much STELARA you need and for how long
- This may depend on your weight
- The usual starting dose is 45 mg ustekinumab. After the starting dose, you will receive the next dose 4 weeks later, and then every 12 weeks
- Patients who weigh more than 100 kg may be given 90 mg instead of 45 mg.

Children and adolescents (under 18 years)

STELARA is not recommended for children and adolescents (under 18 years old) because it has not been studied in this age group.

How STELARA is given

- STELARA is given by injection under your skin (subcutaneously)
- At the start, 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.

Talk to your doctor if you have any questions about giving yourself an injection. See below in section 'Instructions for administration' for further information about how to inject STELARA.

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, the symptoms for which STELARA was prescribed may come back.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, STELARA can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some patients may experience serious side effects and may require treatment.

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- **Signs of an allergic reaction** such as swelling of the face, lips, mouth or throat which may make it difficult to swallow or breathe; skin rash; hives; swelling of the hands, feet or ankles
- **Signs of infection (including tuberculosis)** such as fever, feeling tired or short of breath, cough which will not go away, flu-like symptoms, night sweats, diarrhoea, wounds, dental problems and burning when urinating.

Side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10

- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

The following side effects have been observed with STELARA:

Very common:

- Infection of the throat or airways.

Common:

- Depression
- Feeling dizzy
- Headache
- Sore throat
- Blocked or stuffy nose
- Diarrhoea
- Itching
- Back or muscle pain
- Feeling tired
- Redness of the injection site
- Inflammation of tissue under the skin. The signs include warmth, swelling, redness and pain.

Uncommon:

- Pain, swelling, itching, hardness, bleeding, bruising and irritation where the injection is given.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE STELARA

Keep out of the reach and sight of children.

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

Keep the vial in the outer carton in order to protect from light.

Do not shake STELARA vials. Prolonged vigorous shaking may damage the medicine.

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
- If the liquid is discoloured, cloudy or you can see other foreign particles floating in it (see further section 6 ‘What STELARA looks like and contents of the pack’)
- If you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated)
- If the product has been shaken vigorously
- If the seal is broken.

STELARA is for single use only. Any unused product remaining in the vial and the syringe should be disposed of.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What STELARA contains

- The active substance is ustekinumab. Each vial contains 90 mg ustekinumab (90 mg in 1 ml).
- The other ingredients are sucrose, L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 and water for injections.

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STELARA is a clear to slightly opalescent, 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. Each vial contains 90 mg ustekinumab in 1 ml of solution for injection.

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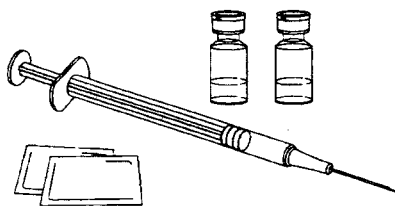
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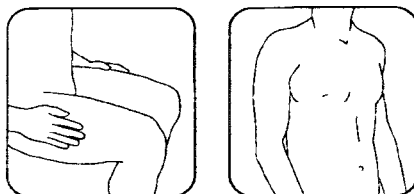
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2. Choose and prepare the injection site:

Choose an injection site

- STELARA is given by injection under your skin (subcutaneously)
- Good places for the injection are the upper thigh or around the belly (abdomen) at least 5 cm away from the navel (belly button)
- If possible, do not use areas of skin that show signs of psoriasis
- If someone will assist in giving you the injection, then he or she may also choose the upper arms or buttocks as an injection site.

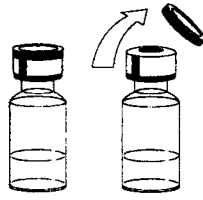


Prepare the injection site

- Wipe the injection site on the skin with an alcohol swab
- **Do not touch this area again before giving the injection.**

3. Prepare the dose:

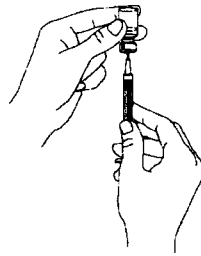
- Take the cap off the top of the vial



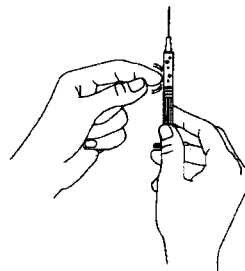
- Do not remove the stopper
- Clean the stopper with an antiseptic swab
- Put the vial on a flat surface.

Remove the needle cover

- Do not touch the needle or let the needle touch anything
- Push the 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 in the vial
- It is important that the needle is always in the liquid. This stops 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



- Then 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. Inject the dose:

- Gently pinch the cleaned skin between your thumb and index finger. Do not squeeze it tightly
- Push the 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
- Press an antiseptic swab over the injection site for a few seconds after the injection.

5. Disposal:

- Used syringes and needles should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your local regulations
- Empty vials, antiseptic wipes, and other supplies can be disposed in your garbage.