Managing Psoriasis with Stelara®

Important information for

Patients

Please read this booklet carefully as it contains important information about Stelara® which has been prescribed by your doctor to treat your psoriasis.

Stelara® (ustekinumab)

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Contents

What is plaque psoriasis?

Plaque psoriasis (pronounced sor-i-a-sis) is a long-term condition causing inflammation and scaly patches of thickened skin called “plaques”. It is caused by a problem with the immune system where white blood cells called T cells, normally activated to fight infections, become activated against healthy skin cells instead.

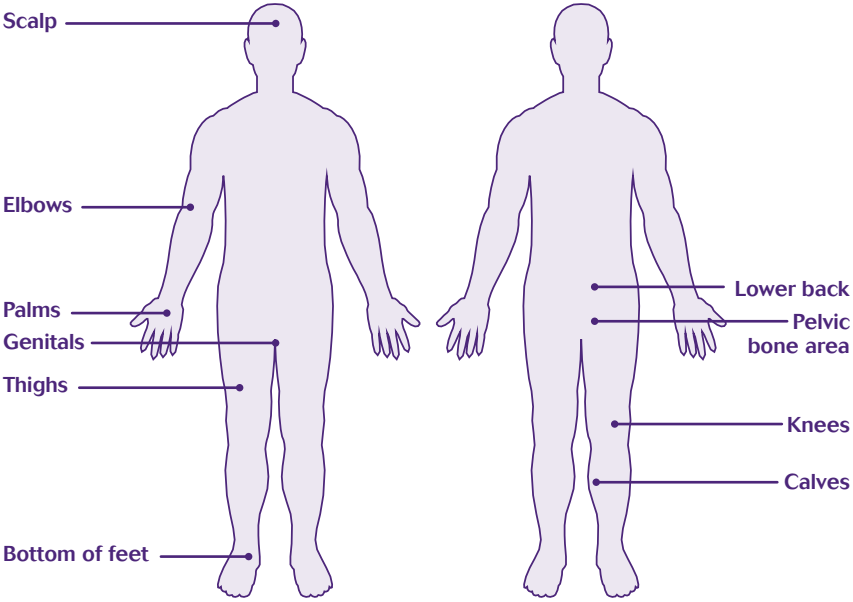
As part of this process the T cells release chemicals called “cytokines”. These cytokines cause inflammation (redness) and make your skin cells divide at a much faster rate than normal. The skin cells then build up and cause the typical thickened, scaly patches. Two particular cytokines, called interleukin-12 and interleukin-23, are increased in psoriasis, causing inflamed skin.

Although psoriasis can appear anywhere on your body, it is most commonly found on your elbows, knees, scalp and lower back. The lesions look like silvery white scales with red skin beneath – the redness is a visible sign of the inflammation that causes the itching and burning. In severe cases, the lesions can even bleed. It is important you tell your doctor all the places where you have psoriasis.

It is also important to understand that although plaque psoriasis may look infected, it is not contagious; people cannot ‘catch it’ by touching the affected areas. Plaque psoriasis is the visible result of an immune system not working properly. It is often inherited, i.e. someone in your family also has psoriasis or carries a gene that causes it. In fact, around a third of people with plaque psoriasis have a relative who also suffers from the condition.

Plaque psoriasis can be triggered or made worse by a variety of factors including a skin injury such as a cut, scrape or sunburn, stress, and some medicines.

Although there are no known ways to prevent plaque psoriasis, there are some things you can do to help make living with it more comfortable. Keep your skin well moisturised. Instead of washing with soap, try unscented cream-based body washes. When washing clothes use gentle detergents and, wherever possible, wear loose cotton-based clothes next to your skin. Sunshine is also good for your skin – just remember to avoid overexposure and use a high factor sunblock.



Common locations of plaque psoriasis

What is Stelara® and how does it work?

Stelara® (ustekinumab) is a treatment for moderate-to-severe plaque psoriasis in adults. Called a biologic, or biological treatment, Stelara® is a monoclonal antibody.

An antibody is a protein produced by your immune system. One of the properties of an antibody is to recognise and bind to one particular place on *one particular kind of molecule*. This property, known as "specificity", allows antibodies to attack infections ("non-self" molecules on bacteria, for example) while leaving your own tissues ("self") unharmed. Monoclonal antibodies are simply multiple copies of a single antibody type.

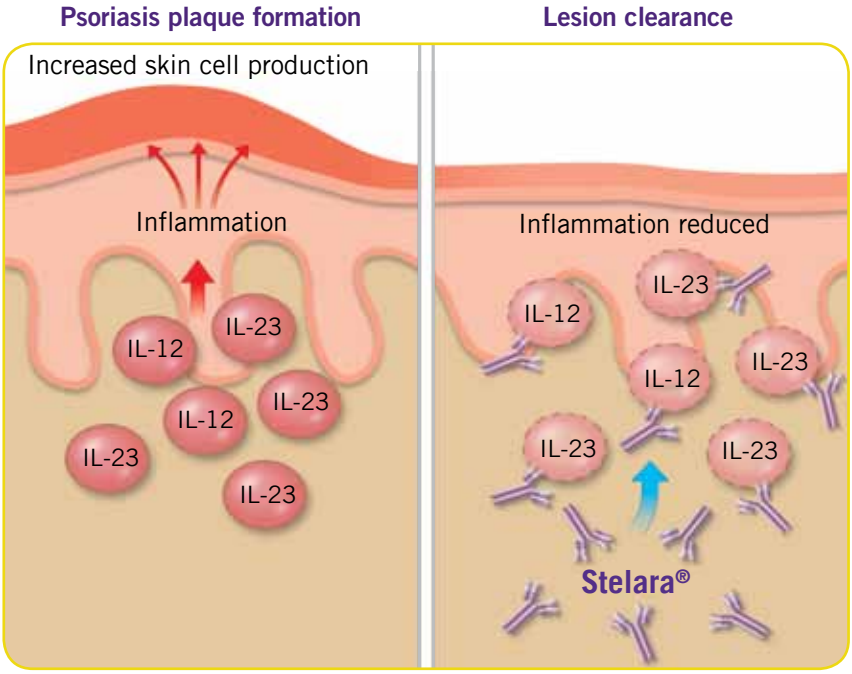
Stelara® works by binding and inactivating the cytokines interleukin-12 and interleukin-23, which are important in psoriasis development and maintenance (see p. 2).

How is Stelara® used?

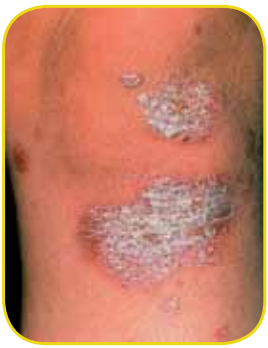
Stelara® is used to treat moderate-to-severe plaque psoriasis in patients who cannot use, or did not respond to, other medicines and phototherapy. Stelara® is not recommended for use in children and adolescents below the age of 18. Because there is a higher incidence of infections in the elderly population (patients aged 65 and older) in general, caution should be used in treating the elderly.

Stelara® is administered by subcutaneous injection. The recommended dose is 45 mg, or 90 mg for patients weighing more than 100 kg. The first two doses ("treatment initiation") are administered 4 weeks apart. Thereafter, you will receive one injection every 12 weeks. Consideration should be given to discontinuing treatment in patients who have shown no response up to 28 weeks of treatment.

Please talk to your healthcare practitioner for more information on self-administration of Stelara®.



Schematic representation of the mode of action of Stelara®



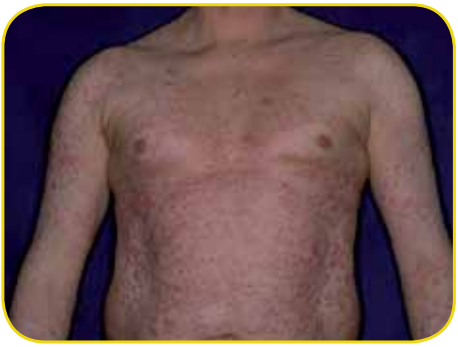


Photo of a plaque and a typical patient

Why should you persist with your Stelara® treatment?

To make sure that you get the full benefit from your treatment with Stelara®, it is important that you follow the regime provided by your doctor. Research has shown that patients who initially respond to Stelara® treatment show sustained improvement with an every-12-week dosing schedule. Patients who discontinue treatment (e.g. who delay or miss an injection) risk a recurrence of psoriatic lesions.

Psoriasis360.com

For more information about psoriasis, please visit:

www.psoriasis360.com

What results can you expect from your Stelara® treatment?

Efficacy in clinical studies

Stelara® has been studied in over 2000 patients with moderate-to-severe plaque psoriasis. The extent and severity of psoriasis lesions before and during treatment was assessed in these studies as a PASI score (PASI = Psoriasis Area and Severity Index). A successful treatment response was defined as at least a 75% reduction in the PASI score – this treatment target is known as PASI 75.

Results of Stelara® treatment vary from patient to patient. However, clinical studies showed that, 12 weeks after starting a course of treatment with Stelara®, two-thirds of patients (45 mg dose, 67%; 90 mg dose, 66–76%) achieved PASI 75. Fewer than 5% of patients receiving placebo (injection with no medicine) improved to this degree. Improvements with Stelara® treatment were apparent after just 2 weeks. Maximum efficacy occurred 20–24 weeks after the first injection, with 75–85% of patients achieving PASI 75.

This treatment effect is sustained so long as the every-12-week dosing schedule is followed. The improvements in PASI were generally maintained for up to 148 weeks.

These studies also recorded the effects of Stelara® on nail psoriasis, quality of life, mental well-being and ability to work – all improved during Stelara® treatment.

Stelara® and your psoriasis

How can you tell if Stelara® is working?

Stelara® will reduce the inflammation and other signs of psoriasis, such as erythema (redness) and scaling. You can usually expect to see improvements within 2–4 weeks of starting Stelara® therapy with maximum effect at Week 20 to Week 24.

To help you and your doctor determine how well you are responding to Stelara® treatment, you can use the body outlines and diary on the calendar in the back pocket of this leaflet to map the size and location of your plaques and record any changes. Remember to bring these with you whenever you visit your doctor.

To make sure you get the full benefit from your Stelara® treatment, it is important to follow your dosing schedule. Please use this calendar to make a note of when your doctor has told you to inject your medication.

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

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.

When self-administering Stelara®, be aware that hypersensitivity reactions could occur.

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, dental problems, a burning sensation when urinating, warm, red and painful skin, or a painful skin rash with blisters**
- **Signs of low blood pressure, such as dizziness or light-headedness.**

The following side-effects have also been observed in clinical trials of Stelara®:

- More than 1 in 10 patients: infection of the throat or airways
- In 1 to 10 per 100 patients: depression; feeling dizzy; headache; sore throat; blocked or stuffy nose; diarrhoea; itching; back, muscle or joint pain; feeling tired; redness of the injection site; inflammation (warmth, swelling, redness and pain) under the skin; rash; itchy bumps
- In 1 to 10 per 1000 patients: shingles, pain, swelling, itching, irritation, bleeding, bruising and hardness at the injection site
- In 1 to 10 per 10,000 patients: serious allergic reactions including anaphylaxis and angioedema (symptoms may include wheezing, dizziness and swelling of the face, lips, mouth or throat which may make it difficult to swallow or breathe); facial palsy, a form of facial paralysis which is usually temporary.

Risk of serious infections includes salmonella, tuberculosis and other mycobacterial infections, and herpes zoster.

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

Important information

Check with your doctor before starting treatment with Stelara® if you have any of the following.

Latex sensitivity

The needle cover of the pre-filled syringe contains latex rubber. This may cause severe allergic reactions in people who are sensitive to latex. Tell your doctor if you have ever had an allergic reaction to latex or developed any allergic reaction to Stelara® injection.

Infections

You must tell your doctor if you have any kind of infection.

This is because Stelara® may make you less able to fight infections. Some infections could become serious.

Tell your doctor even if it is a very minor infection, or if you have any signs that you might be getting an infection. Signs include fever, feeling tired, cough, flu-like symptoms, diarrhoea, dental problems, a burning sensation when urinating, warm, red and painful skin, or a painful skin rash with blisters. 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.

Tell your doctor straight away if you notice any sign of infection as detailed on page 12.

Tuberculosis

Tell your doctor if you have had tuberculosis (TB). Also tell him or her if you have recently been near anyone who might have had TB, or if you have visited regions/countries where TB is common.

Your doctor will examine you and perform a test, according to local regulations, to see if you have TB, before you are given Stelara®.

Stelara® may have the potential to increase the risk of infections and reactivate latent TB.

If your doctor thinks that you are at risk, you may be given medicines for TB. This will be both and during treatment with Stelara®.

Hypersensitivity reactions

In clinical studies of Stelara®, rash and hives (urticaria) have each been observed in less than 2% of patients.

Cancer

Medicines such as 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

Tell your doctor if you receive an 'immunosuppressive medicine' (a medicine that inhibits the activity of your immune system) or phototherapy (when your body is treated with specific ultraviolet [UV] 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.

If you are not sure if any of the above apply, talk to your doctor, pharmacist or nurse before starting treatment with Stelara®. Your doctor will assess your health before treatment. Make sure you tell your doctor about any illness you have.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including vitamins and herbal supplements.

Pregnancy and breastfeeding

Talk to your doctor before starting treatment with 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
- You are breastfeeding or if you plan to breastfeed 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 operate machines.

Useful information

Stelara Summary of Product Characteristics (includes Package Leaflet).

http://www.emea.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000958/WC500058513.pdf. Accessed 16 Aug 2012

Stelara EPAR summary for the public.

http://www.emea.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000958/WC500058509.pdf. Accessed 16 Aug 2012

Notes

Notes

Name: _____

Address: _____

_____

Phone number: _____

Doctor's name: _____

Doctor's address: _____

_____

Doctor's phone number: _____

Use this space to make a note of your doctor's contact details so you can quickly get in touch if you have any questions or concerns about your condition or treatment with Stelara®.

Any Adverse Drug Reactions and Medication Errors should be reported to:

Medicines Authority Post-licensing Directorate 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA. Telephone Number: +356 2343 9000

or at:

http://www.medicinesauthority.gov.mt/adrportal

or to:

A.M. Mangion Ltd Mangion Building, N/S off Valletta Road, Luqa LQA 6000, Malta. Telephone Number: +356 2397 6000. Email: pv@ammangion.com.mt

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Stelara®
(ustekinumab)