Stelara® (ustekinumab) leaflet for patients

Please read this booklet carefully in addition to the Patient Information Leaflet

This booklet contains important information about Stelara®, the treatment that your doctor has prescribed to treat your plaque psoriasis, psoriatic arthritis or Crohn's disease. This leaflet has been written for the person taking the medicine. If you are the parent or caregiver who will give Stelara® to a child, please read this information carefully.

Brochures both for healthcare professionals and patients can be ordered at:

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MALTA
+356 2397 6333

With the support of Janssen Pharmaceutical Companies of Johnson &

Johnson in EMEA Janssen Pharmaceutica NV
Turnhoutseweg 30
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PHMT/STE/0118/0008a

Contents

What is Stelara® and how does it work?

Stelara® (ustekinumab) is a treatment for patients suffering from moderate to severe plaque psoriasis (in adults and adolescents aged 12 years and older), active psoriatic arthritis or Crohn's disease (in adults only). Stelara® is a monoclonal antibody, otherwise known as a biological medicine.

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 the development and maintenance of psoriasis, psoriatic arthritis and Crohn's disease.

How is Stelara® used?

Stelara® can be used to treat three diseases: psoriasis (in adults and adolescents), psoriatic arthritis and Crohn's disease (in adults only).

Specifically:

- Stelara® is indicated to treat moderate to severe plaque psoriasis in adult patients who have been medically advised against continuing other medicines to treat plaque psoriasis or phototherapy
- Stelara® is indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies
- Stelara® is indicated for the treatment of active psoriatic arthritis in adult patients when the response to other non-biological medicines has been inadequate
- Stelara® is indicated for the treatment of adult patients with moderate to severe active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biological therapy or have medical contraindications to such therapies

Stelara® is not recommended for use in children below the age of 12 and 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.

Psoriasis and psoriatic arthritis

Stelara® is administered by subcutaneous injection. Please talk to your healthcare practitioner for more information on self-administration of Stelara®.

In adult patients with plaque psoriasis, the recommended dose of Stelara® is 45 mg, or 90 mg for people 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. In adolescents with psoriasis, the recommended dose is calculated by the weight of the patient at the time of the injection. If you weigh below 60 kg, your healthcare practitioner will guide you on the required amount of Stelara® needed per injection. In adolescent patients weighing between
60 kg and 100 kg, you will receive 45 mg; and for adolescent patients weighing more than 100 kg, you will receive 90 mg. Treatment initiation (the first two doses) and maintenance therapy are administered at the same frequency as adult patients.

In patients with psoriatic arthritis, the recommended dose of Stelara® is an initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter. Alternatively, 90 mg may be used in people with a body weight higher than 100 kg.

Your doctor may consider discontinuing treatment if you have shown no response up to 28 weeks of treatment.

Crohn's disease

During treatment, the first dose of approximately 6 mg/kg Stelara® will be given by your doctor through a drip in a vein in your arm (intravenous infusion).The initial dose is based on body weight.

After the starting dose, you will receive the next dose of 90 mg Stelara® after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously'). In some patients, 90 mg Stelara® may be given every 8 weeks. Your doctor will decide how frequent your doses will be.

If you were receiving Stelara® injections every 12 weeks and your doctor has advised that your doses of Stelara® need to be more frequent, please revert to the dosing timeline for every-8-week dosing. Your next dose should be calculated as 8 weeks after the last dose you received.

Your doctor may consider discontinuing treatment if you have shown no response after up to 16 weeks of treatment.

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

What results can you expect from your Stelara® treatment?

Efficacy in clinical studies in patients with plaque psoriasis

Stelara® has been studied in over 2,000 adult 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 5 years. Patients who discontinue treatment (e.g. who delay or miss an injection) risk a recurrence of psoriatic lesions.

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

Stelara® has been studied in over 100 adolescent patients with moderate to severe psoriasis. As in adult studies, the extent and severity was assessed using the PGA index (PGA = Physician's Global Assessment). The PGA response is measured according to a scale of 0–5, where 0 represents complete clearance of psoriasis. In the study, the treatment target was a PGA response of 0 or 1. In patients treated in the study, over two-thirds of patients showed a PGA 0/1 response compared with placebo (Stelara® 69.4% vs. placebo 5.4%). Improvements were also observed in PASI response and quality of life assessments up to one year of treatment.

Efficacy in clinical studies in patients with psoriatic arthritis

Stelara® has been studied in over 900 patients with active psoriatic arthritis. The impact of treatment with Stelara® was assessed using various measures of psoriatic arthritis disease activity. These included the ACR (American College of Rheumatology) score that measures, among other things, swelling and tenderness of the joints. A successful treatment response was defined as improvements of at least 20% in ACR score (ACR20). Other measures of the efficacy of Stelara® in psoriatic arthritis refer to additional key aspects of the disease including the skin (PASI score).

Data from clinical studies show that 24 weeks after starting treatment with Stelara®, 40–50% of the patients achieved an ACR20 response; a significant difference vs. the patients receiving placebo (20 to 25%). Improvements in patients treated with Stelara® were apparent after 4 weeks. This response, as well as higher responses of 50% improvement (ACR50) and 70% improvement (ACR70), has been shown to be maintained up to at least one year.

Stelara® was also effective on the skin (PASI 75 response in up to 62% of patients receiving the drug compared with up to 5% in patients receiving no drug) and other aspects of the disease such as inflammation where tendons and ligaments join the bone (enthesitis) and inflammation of entire fingers and toes (dactylitis). Damage to patients' bones in their hands and feet was reduced in Stelara®-treated patients and this effect was maintained up to one year. Stelara® was also shown to be effective on physical function, quality of life and fatigue.

Efficacy in clinical studies in patients with Crohn's disease

Stelara® has been studied in over 1,300 patients with active Crohn's disease. The impact of treatment with Stelara® was assessed using the Crohn's Disease Activity Index (CDAI) score as a measure of Crohn's disease activity. A successful treatment response was defined as a reduction from baseline in CDAI score of at least 100 points (CDAI100). Other measures of the efficacy of Stelara® in Crohn's disease refer to additional key aspects of the disease including mucosal healing and biomarkers.

Data from clinical studies show that 6 weeks after induction therapy with Stelara®, up to 50% of the patients achieved a CDAI100 response; a significant difference vs. the patients receiving placebo (15 to 20%). This response, as well as remission (defined as CDAI score <150 points), has been shown to be maintained up to week 44 in the maintenance.

Improvements of symptoms as well as biomarkers in patients treated with Stelara® were apparent already after 3 weeks.

Half of the patients who responded after induction therapy were in remission at week 44.

Stelara® and your disease

Why should you persist with your Stelara® treatment?

To make sure you get the full benefit from your Stelara® treatment, it is important to follow your dosing schedule. Please use the calendar at the end of this leaflet to make a note of when your next injection is due.

For psoriasis and psoriatic arthritis your doctor may consider discontinuing treatment if you have shown no response after 28 weeks of treatment. For Crohn's disease your doctor may consider discontinuing treatment if you have shown no response up to 16 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 that 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. These may be signs of infection such as a chest infection, or skin infection, or shingles and could have serious complications

- Signs of infections of the chest (lower respiratory tract infections), such as cough, mucus discharge, high temperature, dizziness, feeling a pressure or heaviness in your chest, shortness of breathing, or breathing at an increased rate. A blocked nose, watering nose, and increased heart-beat can also be symptoms of lower respiratory tract infection.
- Signs of low blood pressure, such as dizziness or light-headedness

The following side effects of Stelara® have been observed in clinical trials and in patients treated with of Stelara® outside of clinical trials:

- In 1 to 10 per 100 patients: infection of the nose, throat or airways, dizziness, headache, pain in your throat, diarrhoea, nausea, vomiting, itching, back, muscle or joint pain, fatigue, pain or redness around the injection site
- In 1 to 10 per 1000 patients: tooth infections, vaginal yeast infection, swelling, itching, irritation, bleeding, bruising and hardness at the injection site, bacterial infection of the skin called cellulitis, shingles, viral infection of your nose and throat, infections of the chest, rash, urticaria, blocked or stuffy nose, depression, feeling weak, acne, skin exfoliation (can look like the symptoms of psoriasis, with increased shedding of skin cells) and pustular psoriasis (a rare form of psoriasis characterised by pus-filled spots). Uncommon occurrences of facial palsy (a form of facial paralysis that is usually temporary) have been recorded with Stelara® treatment
- 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). Rare occurrences of exfoliative dermatitis (a collective name for types of skin conditions that include excess shedding of skin cells) and erythrodermic psoriasis (a rare form of psoriasis where the skin of the whole body becomes red and is often associated with fever) have been reported

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

Stelara® is not recommended for use in children below the age of 12.

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 as soon as possible.

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 reactions 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 straight away 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 or short of breath; cough that 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. If you are not sure about any symptoms you are experiencing, it is important that you talk to your doctor as soon as possible.

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 and 13.

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 before and during treatment with Stelara®.

Hypersensitivity reactions

In clinical studies of Stelara®, rash and hives (urticaria) have each been observed in less than 1% of patients. You should contact your doctor immediately if you experience hypersensitivity reactions as you may need urgent medical treatment.

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.

Skin disorders

Medicines such as Stelara® that are used to treat plaque psoriasis can lead to unwanted effects on the skin. Sometimes these events are difficult to identify and may naturally occur as part of your psoriasis. Unwanted skin effects that have been seen in patients treated with Stelara® can include skin exfoliation (increased shedding of skin cells), exfoliative dermatitis (redness and shedding of skin over a larger area of the body, which may be itchy or painful), pustular psoriasis (a change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever) and erythrodermic psoriasis (similar symptoms to exfoliative dermatitis that sometimes develop as a natural change in the type of psoriasis symptoms). You should contact your doctor immediately if any changes in your skin occur following treatment with Stelara®.

Nervous system disorders

Uncommon incidences of facial palsy (drooping eyelid and sagging muscles on one side of the face ['facial palsy' or 'Bell's palsy'], which is usually temporary) have been recorded in patients treated with Stelara®. You should tell your doctor immediately if you begin to notice symptoms following treatment with Stelara®.

Vaccinations

Tell your doctor if you have recently had or are going to have a vaccination.

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®.

In general, caution should be exercised when considering concomitant use of these drugs and Stelara®. However, if you suffer from psoriatic arthritis and you receive an immunosuppressive medicine called methotrexate, concomitant methotrexate use does not appear to influence the safety or efficacy of Stelara®. 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

Stelara® has no or negligible influence on the ability to drive and use machines.

Pharmacovigilance Contacts:
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Tel: +356 2397 6333

Reporting of suspected adverse reactions
Website: www.medicinesauthority.gov.mt/adrportal

Malta Medicines Authority
Sir Temi Żammit Buildings,
Malta Life Sciences Park,
San Ġwann SĠN 3000
Malta
E-mail: info.medicinesauthority@gov.mt
Telephone: 356 2343 9000 (from 7:30 to 15:45)
Helpline: 356 2343 9111 (from 9:00 to 12:00)
Fax: 356 2343 9161

For medical queries, kindly contact AM Mangion Ltd on +356 2397 6888

Injection calendar

Year_____

Month 1	Notes
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Month 2	Notes
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Month 3	Notes
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Month 4	Notes
Week 1	
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Week 3	
Week 4	
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Month 5	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Month 6	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Injection calendar

Year_____

Month 7	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Month 8	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Month 9	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Month 10	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Month 11	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Month 12	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Injection calendar

Year_____

Month 1	Notes
Week 1	
Week 2	
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Week 4	
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Week 4	
Week 5	

Injection calendar

Year_____

Month 7	Notes
Week 1	
Week 2	
Week 3	
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Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

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Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Injection calendar

Year_____

Month 1	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

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Week 1	
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Week 2	
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Week 4	
Week 5	

Month 6	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Injection calendar

Year_____

Month 7	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

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Week 1	
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Week 4	
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Week 1	
Week 2	
Week 3	
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Week 5	

Injection calendar

Year_____

Month 1	Notes
Week 1	
Week 2	
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Week 5	

Injection calendar

Year_____

Month 7	Notes
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	

Month 8	Notes
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Week 3	
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Injection calendar

Year_____

Month 1	Notes
Week 1	
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Injection calendar

Year_____

Month 7	Notes
Week 1	
Week 2	
Week 3	
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Injection calendar

Year_____

Month 1	Notes
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Month 5	Notes
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Month 6	Notes
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Injection calendar

Year_____

Month 7	Notes
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Month 10	Notes
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Month 11	Notes
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Month 12	Notes
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Notes

Name: _____

Address: _____

Phone number: _____

Doctor's name: _____

Doctor's address: _____

Doctor's phone number: _____

Pharmacovigilance Contacts:

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