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Stelara (*ustekinumab*)

An overview of Stelara and why it is authorised in the EU

What is Stelara and what is it used for?

Stelara is a medicine used to treat:

- moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin). It is used in adults and children above the age of 6 years whose condition has not improved with, or who cannot use, other systemic (whole-body) psoriasis treatments, such as ciclosporin, methotrexate or PUVA (psoralen ultraviolet A). PUVA is a type of treatment where the patient receives a medicine called psoralen, before being exposed to ultraviolet light;
- active psoriatic arthritis (inflammation of the joints associated with psoriasis) in adults, when the condition has not improved enough with other treatments called disease-modifying anti-rheumatic drugs (DMARDs). Stelara may be used alone or combined with methotrexate (a DMARD);
- moderately to severely active Crohn's disease (a disease-causing inflammation of the gut) in adults and children weighing at least 40 kg whose condition has not improved enough with other treatments or who cannot receive such treatments;
- moderately to severely active ulcerative colitis (inflammation of the large intestine causing ulceration and bleeding) in adults whose condition has not improved enough with other treatments for ulcerative colitis or who cannot receive such treatments.

Stelara contains the active substance ustekinumab.

How is Stelara used?

Stelara can only be obtained with a prescription and should be given under the supervision of a doctor who has experience in diagnosing and treating the diseases that Stelara is used for.

In plaque psoriasis and psoriatic arthritis, Stelara is injected under the skin. The first injection is followed by another injection 4 weeks later. After that, one injection is given every 12 weeks.

In Crohn's disease and ulcerative colitis, Stelara treatment is started as an infusion (drip) into a vein lasting at least 1 hour. Eight weeks after the first infusion, Stelara is given as an injection under the skin. Patients then continue with Stelara injected under the skin every 8 or 12 weeks, depending on how well the treatment is working.

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Patients or their caregivers may inject Stelara once they have been trained, if their doctor thinks that this is appropriate. For more information about using Stelara, see the package leaflet or contact your doctor or pharmacist.

How does Stelara work?

The active substance in Stelara, ustekinumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific target in the body. Ustekinumab attaches to 2 messenger molecules in the immune system called interleukin 12 and interleukin 23. Both are involved in inflammation and other processes that are important in psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. By attaching to them and blocking their activity, ustekinumab reduces the activity of the immune system and the symptoms of the disease.

What benefits of Stelara have been shown in studies?

Plaque psoriasis

In the treatment of moderate to severe plaque psoriasis, Stelara was more effective than placebo (a dummy treatment) in 2 main studies involving a total of 1,996 adults. In over half of these patients, other treatments for psoriasis had not worked, were not tolerated or could not be taken by the patients. The main measure of effectiveness was the number of patients whose symptom score improved by 75% or more after 12 weeks. Taking the results of the 2 main studies in adults together, symptoms improved in around 69% of the patients receiving Stelara after 12 weeks, compared with around 3% of the patients receiving placebo.

Longer-term results from these studies showed that with continuous treatment for 5 years, improvement of symptoms with Stelara is maintained. A study comparing Stelara with etanercept (another medicine used for psoriasis) found that Stelara is more effective than etanercept after 12 weeks of treatment.

Two studies were carried out in children with moderate to severe plaque psoriasis. The main measure of effectiveness for both studies was the number of patients whose symptom score improved after 12 weeks of treatment. The first study involved 110 children aged between 12 and 18 years. The children received placebo or Stelara. Around 69% of children who received Stelara achieved a score of cleared or minimal, compared with 5% of patients receiving placebo. The second study involved 44 children aged between 6 and 11 years, all of whom received Stelara. Around 77% of children achieved a score of cleared or minimal. In this study, Stelara was not compared with placebo or another treatment.

Psoriatic arthritis

In the treatment of active psoriatic arthritis, Stelara was compared with placebo in 2 main studies involving a total of 927 adults whose condition was not controlled well enough with previous treatments. In both studies, the main measure of effectiveness was the number of patients whose symptom score improved after 24 weeks. In the first study, the symptom score improved in around 42% of those given Stelara 45 mg and 50% of those given 90 mg, compared with around 23% of those given placebo. In the second study, the symptom score improved in around 44% of those given either dose of Stelara, compared with around 20% of those given placebo.

Crohn's disease

Adults

In the treatment of Crohn's disease, Stelara (given by infusion) was compared with placebo in 2 main studies involving 1,369 adults with moderately to severely active disease. The main measure of effectiveness was the number of patients whose symptom score improved 6 weeks after the infusion. In the first study, the symptom score improved in around 34% patients who received Stelara compared with 21% of patients receiving placebo. In the second study the results were 56% for Stelara and 29% for placebo.

Some patients from the 2 main studies went on to receive Stelara (injected under the skin), given either every 8 or 12 weeks, or placebo. After 44 weeks of starting treatment by injection under the skin, 53% of patients given Stelara every 8 weeks and 49% of patients given Stelara every 12 weeks had a significant reduction in symptoms of Crohn's disease, compared with 36% of patients given placebo.

Children

A main study involved 48 children with moderately to severely active Crohn's disease, whose condition was not controlled well enough with previous treatments or who could not receive such treatments. The children received one dose of Stelara given by infusion followed by injections under the skin every 8 or 12 weeks over 44 weeks. The results showed that 8 weeks after receiving the infusion, symptoms were gone or almost gone in 52% (25 out of 48) of children. Supportive data showed that this figure remained the same at the end of the study. The study did not compare Stelara with placebo or any other treatment.

Ulcerative colitis

In the treatment of ulcerative colitis, Stelara (given by infusion) was compared with placebo in 2 main studies. The first study involved 961 patients with moderately to severely active disease. The main measure of effectiveness was the number of patients whose symptoms were gone or almost gone 8 weeks after the infusion. Symptoms were gone or almost gone in 16% of patients who received Stelara compared with 5% of patients receiving placebo.

In the second study, a total of 523 patients from the first study whose symptoms had improved with Stelara went on to receive the medicine (injected under the skin), given either every 8 or 12 weeks, or placebo. After 44 weeks of starting treatment, symptoms of ulcerative colitis were gone or almost gone in 44% of patients given Stelara every 8 weeks and 38% of patients given Stelara every 12 weeks, compared with 24% of patients given placebo.

What are the risks associated with Stelara?

For the full list of side effects and restrictions with Stelara, see the package leaflet.

The most common side effects with Stelara (seen in more than 1 in 20 during clinical trials) include headache and nasopharyngitis (inflammation of the nose and throat). The most serious side effect reported with Stelara is serious hypersensitivity (allergic reaction).

Stelara must not be used in patients who have an active infection that the doctor considers important.

Why is Stelara approved?

The European Medicines Agency decided that Stelara's benefits are greater than its risks and it can be authorised for use in the EU.

The Agency considered that studies had shown that Stelara was effective in the treatment of adults and children over 6 years of age with moderate to severe plaque psoriasis in whom other treatments had not worked or could not be used.

For adults with psoriatic arthritis whose condition had not improved enough with DMARDs, the Agency noted that limited treatments were available and considered that Stelara would be of benefit in these patients.

In Crohn's disease, the effects of Stelara in reducing symptoms in patients in whom other treatments had not worked or could not be used were considered important, also given the unmet medical need of these patients. The side effects of the medicine were considered manageable.

In ulcerative colitis, studies showed that Stelara was effective in the treatment of patients in whom other treatments had not worked or could not be used. The side effects were as expected for this medicine.

What measures are being taken to ensure the safe and effective use of Stelara?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Stelara have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Stelara are continuously monitored. Side effects reported with Stelara are carefully evaluated and any necessary action taken to protect patients.

Other information about Stelara

Stelara received a marketing authorisation valid throughout the EU on 16 January 2009.

Further information on Stelara can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/stelara.

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