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EPAR summary for the public

Stelara

ustekinumab

This is a summary of the European public assessment report (EPAR) for Stelara. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Stelara.

For practical information about using Stelara, patients should read the package leaflet or contact their doctor or pharmacist.

What is Stelara and what is it used for?

Stelara is a medicine used to treat the following diseases:

- 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 12 years whose condition has not responded to 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 containing a compound called a 'psoralen' before being exposed to ultraviolet light.
- active psoriatic arthritis (inflammation of the joints associated with psoriasis) in adults, when the condition has not responded well enough to 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 whose condition has not responded well enough to other treatments for Crohn's disease 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.

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Stelara is available as a solution for injection (45 and 90 mg) in vials or prefilled syringes and as a concentrate (130 mg) to make a solution for infusion (drip) into a vein.

In plaque psoriasis and psoriatic arthritis, Stelara is given as an injection under the skin. For adults the usual dose is 45 mg, whereas the dose in children depends on bodyweight. The first injection is followed by a further injection four weeks later, and then an injection every 12 weeks. Patients weighing over 100 kg should be given Stelara in 90-mg doses for psoriasis, and this should also be considered for psoriatic arthritis.

In Crohn's disease, treatment is started with Stelara concentrate. The infusion lasts at least one hour and the dose depends on the patient's bodyweight. Eight weeks after the first infusion patients should receive 90 mg Stelara by injection under the skin. Patients then continue with Stelara given under the skin every 8 or 12 weeks depending on response to treatment.

Patients or their caregivers may inject Stelara under the skin once they have been trained, if their doctor thinks that this is appropriate. For further information, see the package leaflet.

How does Stelara work?

The active substance in Stelara, ustekinumab, is a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Ustekinumab attaches to two cytokines (messenger molecules) in the immune system called interleukin 12 and interleukin 23. These cytokines are involved in inflammation and other processes that are important in psoriasis, psoriatic arthritis and Crohn's disease. By 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 has been compared with placebo (a dummy treatment) in two main studies involving a total of 1,996 adults with the condition. In over half of these patients other treatments for psoriasis had failed or the patients could not receive them. The main measure of effectiveness was the number of patients who 'responded' to treatment after 12 weeks, meaning that symptom scores improved by 75% or more. Stelara was more effective than placebo at improving the symptoms of plaque psoriasis. Looking at the results of the two main studies in adults taken together, around 69% of the patients receiving Stelara responded to treatment after 12 weeks, compared with around 3% of the patients receiving placebo.

The company subsequently provided the longer-term results of the studies (after 5 years of treatment), and the results of a study comparing Stelara with etanercept (another medicine for psoriasis). The longer-term results showed that with continuous treatment, the response to Stelara is maintained over 5 years. The comparative study showed that Stelara is more effective than etanercept after 12 weeks of treatment.

An additional study involved 110 children with moderate to severe plaque psoriasis aged between 12 and 18 years. The children received placebo or Stelara and the main measure of effectiveness was the number of patients who responded to treatment after 12 weeks as shown by an improvement in symptom scores. In around 69% of children (25 out of 36) who received Stelara responded, compared with 5% of patients receiving placebo (2 out of 37).

Psoriatic arthritis

In the treatment of active psoriatic arthritis, Stelara was compared with placebo in two main studies involving a total of 927 adults with the condition who did not have an adequate response with previous treatments. In both studies the main measure of effectiveness was the number of patients who responded to treatment after 24 weeks as shown by an improvement in symptom scores. In the first study, around 42% of those given Stelara 45 mg and 50% of those given 90 mg responded, compared with around 23% of those given placebo. In the second study, around 44% of those given either dose of Stelara responded, compared with around 20% of those given placebo.

Crohn's disease

In the treatment of Crohn's disease, Stelara (concentrate for infusion) was compared with placebo in two main studies involving 1,369 patients with moderately to severely active disease. In both studies the main measure of effectiveness was the number of patients who responded to treatment 6 weeks after the injection as shown by an improvement in symptom scores. In the first study, around 34% patients who received Stelara (at a dose calculated based on bodyweight) responded to treatment compared with 21% of patients who were given placebo. In the second study the figures were 56% for Stelara and 29% for placebo.

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

What are the risks associated with Stelara?

The most common side effects with Stelara (seen in more than 5% of patients during clinical trials) are headache and nasopharyngitis (inflammation of the nose and throat). Most of these effects were considered mild and did not require treatment to be stopped. The most serious side effect reported with Stelara is serious hypersensitivity (allergic reaction). For the full list of all side effects reported with Stelara, see the package leaflet.

Stelara must not be used in patients who have an active infection that the doctor considers important. For the full list of restrictions please see the package leaflet.

Why is Stelara approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Stelara's benefits are greater than its risks and recommended that it be approved for use in the EU.

The CHMP considered that studies had shown that Stelara was effective in the treatment of adults and children over 12 years of age with moderate to severe plaque psoriasis. However, patients in some studies had unexpected increases in problems affecting the heart and blood vessels and psychiatric problems such as depression which might be related to Stelara. Therefore, the CHMP decided to restrict the use of the medicine in moderate to severe plaque psoriasis to patients aged 12 years and above in whom other treatments had failed or who could not receive them.

For adults with psoriatic arthritis who have not responded well to DMARDs the CHMP noted the limited treatments 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 failed or who could not receive them were considered important, also given the unmet medical need of these patients. The side effects of the medicine were considered tolerable and manageable.

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

The company that makes Stelara will also provide educational material for healthcare providers and patients. These will focus on the safety of Stelara, particularly the risks of developing tuberculosis, other infections and cancers. The patient material will also include details of how Stelara should be injected under the skin.

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

Other information about Stelara

The European Commission granted a marketing authorisation valid throughout the European Union for Stelara on 16 January 2009.

The full EPAR for Stelara can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Stelara, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2016.