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Steqeyma (*ustekinumab*)

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

What is Steqeyma and what is it used for?

Steqeyma 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 whose condition has not improved enough with other treatments for Crohn's disease or who cannot receive such treatments;

Steqeyma contains the active substance ustekinumab and is a biological medicine. It is a 'biosimilar medicine'; this means that Steqeyma is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Steqeyma is Stelara. For more information on biosimilar medicines, see here.

How is Steqeyma used?

Steqeyma 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 Steqeyma is used for.

In plaque psoriasis and psoriatic arthritis, Steqeyma is injected under the skin. The dose depends on the patient's bodyweight. Children under 60 kg who need lower doses should use another medicine containing the same active substance (ustekinumab) which allows the dose to be adjusted as needed. The first injection is followed by a further injection 4 weeks later, and then an injection every 12 weeks.

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In Crohn's disease in adults, treatment is started with Steqeyma infusion (drip) into a vein over at least 1 hour. The dose depends on the patient's bodyweight and is given every 8 or 12 weeks depending on how well the treatment is working.

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

How does Steqeyma work?

The active substance in Steqeyma, 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 two 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 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 Steqeyma have been shown in studies?

Laboratory studies comparing Steqeyma with Stelara have shown that the active substance in Steqeyma is highly similar to that in Stelara in terms of structure, purity and biological activity. Studies have also shown that giving Steqeyma produces similar levels of the active substance in the body to giving Stelara.

In addition, a study of 509 patients with moderate to severe plaque psoriasis showed that Steqeyma was as effective as Stelara in improving symptoms. The improvement in symptoms scores after 12 weeks was similar with both medicines.

Because Steqeyma is a biosimilar medicine, the studies on effectiveness of ustekinumab carried out with Stelara do not all need to be repeated for Steqeyma.

What are the risks associated with Steqeyma?

The safety of Steqeyma has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Stelara.

For the complete list of side effects and restrictions of Steqeyma, see the package leaflet.

The most common side effects with ustekinumab (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 ustekinumab include serious hypersensitivity (allergic reaction).

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

Why is Steqeyma authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Steqeyma has a highly similar structure, purity and biological activity to Stelara and is distributed in the body in the same way. In addition, a study in plaque psoriasis has shown that Steqeyma and Stelara are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Steqeyma will have the same effects as Stelara in its authorised uses. Therefore, the Agency's view was that, as for Stelara, the benefits of Steqeyma outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Steqeyma

Steqeyma received a marketing authorisation valid throughout the EU on 22 August 2024.

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

This overview was last updated in 09-2024.