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Eksunbi (*ustekinumab*)

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

What is Eksunbi and what is it used for?

Eksunbi 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). Eksunbi 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;
- 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.

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

How is Eksunbi used?

Eksunbi 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 Eksunbi is used for.

In plaque psoriasis and psoriatic arthritis, Eksunbi is injected under the skin. 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 and ulcerative colitis, treatment is started with Eksunbi infusion (drip) into a vein over at least 1 hour. Eight weeks after the first infusion, Eksunbi is injected under the skin. Patients then continue with Eksunbi injected under the skin every 8 or 12 weeks depending on how well the treatment is working.

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

How does Eksunbi work?

The active substance in Eksunbi, 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 blocking their activity, ustekinumab reduces the activity of the immune system and the symptoms of the disease.

What benefits of Eksunbi have been shown in studies?

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

In addition, a study of 503 patients with moderate to severe plaque psoriasis showed that Eksunbi was as effective as Stelara in improving symptoms. The improvement in symptoms scores after 12 weeks was similar with both medicines.

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

What are the risks associated with Eksunbi?

The safety of Eksunbi 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 Eksunbi, see the package leaflet.

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

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

Why is Eksunbi authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Eksunbi 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 patients with plaque psoriasis has shown that Eksunbi and Stelara are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Eksunbi will have the same effects as Stelara in its authorised uses. Therefore, the Agency's view was that, as for Stelara, the benefits of Eksunbi 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 Eksunbi?

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

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

Other information about Eksunbi

Eksunbi received a marketing authorisation valid throughout the EU on 12-09-2024.

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

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