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Absimky (*ustekinumab*)

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

What is Absimky and what is it used for?

Absimky 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). Absimky 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.

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

How is Absimky used?

Absimky 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 Absimky is used for.

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

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

How does Absimky work?

The active substance in Absimky, 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 Absimky have been shown in studies?

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

In addition, a study of 523 patients with moderate to severe plaque psoriasis showed that Absimky was as effective as Stelara in improving symptoms. The improvement in symptoms scores after 8 weeks was similar with both medicines.

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

What are the risks associated with Absimky?

The safety of Absimky 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 Absimky, 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) including anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness).

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

Why is Absimky authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Absimky 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 Absimky and Stelara are equivalent in terms of safety and effectiveness in this condition.

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

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

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

Other information about Absimky

Absimky received a marketing authorisation valid throughout the EU on 12 December 2024.

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

This overview was last updated in 12-2024.