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Uzpruvo (*ustekinumab*)

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

What is Uzpruvo and what is it used for?

Uzpruvo 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 from 6 years of age whose condition has not improved enough 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). Uzpruvo 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.

Uzpruvo is a 'biosimilar medicine'. This means that Uzpruvo is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Uzpruvo is Stelara. For more information on biosimilar medicines, see here.

Uzpruvo contains the active substance ustekinumab.

How is Uzpruvo used?

Uzpruvo 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 Uzpruvo is used for.

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

In Crohn's disease, treatment must be started as an infusion (drip) into a vein lasting at least 1 hour. Eight weeks after the first infusion, Uzpruvo is given as an injection 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 Uzpruvo under the skin once they have been trained, if their doctor thinks that this is appropriate.

For more information about using Uzpruvo, see the package leaflet or contact your doctor or pharmacist.

How does Uzpruvo work?

The active substance in Uzpruvo, 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 and Crohn's disease. 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 Uzpruvo have been shown in studies?

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

In addition, a study involving 581 people with moderate to severe chronic plaque psoriasis showed that Uzpruvo was as effective as Stelara. After 12 weeks of treatment, PASI scores (a measure of disease severity and area of skin affected) had improved by around 87% in both Uzpruvo and Stelara groups.

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

What are the risks associated with Uzpruvo?

The safety of Uzpruvo 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 Uzpruvo, see the package leaflet.

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

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

Why is Uzpruvo authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Uzpruvo 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 moderate to severe plaque psoriasis has shown that the safety and effectiveness of Uzpruvo is equivalent to that of Stelara in this indication.

All these data were considered sufficient to conclude that Uzpruvo will behave in the same way as Stelara in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was

that, as for Stelara, the benefits of Uzpruvo 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 Uzpruvo?

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

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

Other information about Uzpruvo

Uzpruvo received a marketing authorisation valid throughout the EU on 5 January 2024.

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

This overview was last updated in 03-2026.