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Usymro (*ustekinumab*)

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

What is Usymro and what is it used for?

Usymro 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 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). Usymro 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.

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

How is Usymro used?

Usymro can only be obtained with a prescription and should be used under the supervision of a doctor who has experience in diagnosing and treating the diseases that Usymro is used for.

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

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

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

How does Usymro work?

The active substance in Usymro, 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 these diseases.

What benefits of Usymro have been shown in studies?

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

In addition, a study of 556 adults with moderate to severe plaque psoriasis showed that Usymro was as effective as Stelara at improving symptoms of the disease. After 8 weeks of treatment, PASI scores (a measure of disease severity and area of skin affected) had improved by around 76% in people receiving Usymro and around 77% in those receiving Stelara.

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

What are the risks associated with Usymro?

For the full list of side effects and restrictions with Usymro, see the package leaflet.

The safety of Usymro 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.

The most common side effects with ustekinumab (which may affect more to 1 in 20 people) include headache and nasopharyngitis (inflammation of the nose and throat). The most serious side effect with ustekinumab (which may affect up to 1 in 1,000 people) is serious hypersensitivity reaction (allergic reaction) including anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness).

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

Why is Usymro approved?

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

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

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

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

Other information about Usymro

Usymro received a marketing authorisation valid throughout the EU on 14 August 2025.

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

This overview was last updated in 07-2025.