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Qoyvolma (*ustekinumab*)

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

What is Qoyvolma and what is it used for?

Qoyvolma 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 and 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). Qoyvolma 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;
- 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.

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

How is Qoyvolma used?

Qoyvolma 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 Qoyvolma is used for.

Qoyvoma is given as an infusion (drip) into a vein or an injection under the skin with a pre-filled syringe.

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In plaque psoriasis and psoriatic arthritis, Qoyvolma 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 and ulcerative colitis, treatment is started as an infusion into a vein lasting at least 1 hour. Eight weeks after the first infusion, Qoyvolma is given as an injection under the skin. Patients then continue with Qoyvolma injected under the skin every 8 or 12 weeks depending on how well the treatment is working.

Patients or their caregivers may inject Qoyvolma once they have been trained, if their doctor thinks that this is appropriate.

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

How does Qoyvolma work?

The active substance in Qoyvolma, 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 attaching to them and blocking their activity, ustekinumab reduces the activity of the immune system and the symptoms of the diseases.

What benefits of Qoyvolma have been shown in studies?

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

In addition, a study in 509 patients with moderate to severe plaque psoriasis showed that Qoyvolma is as effective as Stelara in improving symptoms of the disease. After 12 weeks of treatment, patients' symptom scores improved similarly with both medicines.

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

What are the risks associated with Qoyvolma?

The safety of Qoyvolma has been evaluated and, based on all studies carried out, its side effects are considered comparable to those of Stelara.

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

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

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

Why is Qoyvolma authorised in the EU?

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

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

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

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

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

Other information about Qoyvolma

Qoyvolma received a marketing authorisation valid throughout the EU on 2 June 2025.

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

This overview was last updated in 10-2025.