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Yesintek (*ustekinumab*)

A plain language overview of Yesintek and why it is authorised in the EU

What is Yesintek and what is it used for?

Yesintek 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 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). Yesintek 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.

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

How is Yesintek used?

Yesintek can only be obtained with a prescription and should be given under the supervision of a doctor experienced in diagnosing and treating the diseases that Yesintek is used for.

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

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

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

How does Yesintek work?

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

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

In addition, a study involving 384 adults with moderate to severe plaque psoriasis showed that Yesintek was as effective as Stelara at improving symptoms of the disease. The improvement in symptoms scores after 12 weeks was similar with both medicines.

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

Studies carried out with Yesintek are described in more detail in the medicine's assessment reports.

What are the side effects and restrictions with Yesintek?

The safety of Yesintek has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of Stelara.

For the complete list of side effects and restrictions of Yesintek, 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 with ustekinumab (which may affect up to 1 in 1,000 people) is serious hypersensitivity (allergic reaction), including anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness).

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

Why is Yesintek authorised in the EU?

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

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

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

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

Other information about Yesintek

Yesintek received a marketing authorisation valid throughout the EU on 14 February 2025.

Further information on Yesintek, including the package leaflet and assessment reports, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Yesintek.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 07-2026.