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Pyzchiva (*ustekinumab*)

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

What is Pyzchiva and what is it used for?

Pyzchiva 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). Pyzchiva may be used alone or in combination 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.

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

Pyzchiva contains the active substance ustekinumab.

How is Pyzchiva used?

Pyzchiva 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 Pyzchiva is used for.

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

In Crohn's disease, treatment is started with Pyzchiva infusion (drip) into a vein over at least 1 hour. Eight weeks after the infusion, Pyzchiva is injected under the skin. Patients then continue with one 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 Pyzchiva under the skin once they have been trained to do so and if their doctor thinks that this is appropriate.

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

How does Pyzchiva work?

The active substance in Pyzchiva, 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 play a role in psoriasis, psoriatic arthritis and Crohn's disease. By blocking their activity, ustekinumab reduces the activity of the immune system and the symptoms of the disease.

What benefits of Pyzchiva have been shown in studies?

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

In addition, a study involving 503 people with moderate to severe chronic plaque psoriasis showed that Pyzchiva was as effective as Stelara in improving symptoms of the disease. After 12 weeks of treatment, PASI scores (a measure of disease severity and area of skin affected) had improved by around 86% in both Pyzchiva and Stelara groups.

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

What are the risks associated with Pyzchiva?

The safety of Pyzchiva 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 Pyzchiva, see the package leaflet.

The most common side effects with Pyzchiva (which may affect more than 5 in 100 people) include headache and nasopharyngitis (inflammation of the nose and throat).

Why is Pyzchiva authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Pyzchiva has a highly similar structure, purity and biological activity to Stelara and is distributed in the body in the same way. In addition, studies in moderate to severe chronic plaque psoriasis have shown that Pyzchiva and Stelara are equivalent in terms of safety and effectiveness.

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

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

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

Other information about Pyzchiva

Pyzchiva received a marketing authorisation valid throughout the EU on 19 April 2024.

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

This overview was last updated in 09-2024.