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Wezenla (*ustekinumab*)

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

What is Wezenla and what is it used for?

Wezenla 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). Wezenla 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.

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

How is Wezenla used?

Wezenla 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 Wezenla is used for.

In plaque psoriasis and psoriatic arthritis, Wezenla 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, treatment is started Wezenla as an infusion (drip) into a vein lasting at least 1 hour. Eight weeks after the first infusion, Wezenla is given as an injection under the skin. Patients then continue with Wezenla 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 Wezenla once they have been trained, if their doctor thinks that this is appropriate. For more information about using Wezenla, see the package leaflet or contact your doctor or pharmacist.

How does Wezenla work?

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

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

In addition, a study in 563 patients with moderate to severe plaque psoriasis showed that Wezenla was as effective as Stelara in treating this condition. After 12 weeks improvement in symptom scores (PASI) was around 82% in patients given either of these medicines.

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

What are the risks associated with Wezenla?

The safety of Wezenla 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 Wezenla, see the package leaflet.

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

Why is Wezenla authorised in the EU?

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

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

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

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

Other information about Wezenla

Wezenla received a marketing authorisation valid throughout the EU on 20 June 2024.

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

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