EMA/91614/2024
EMEA/H/C/006208

Apremilast Accord (*apremilast*)

An overview of Apremilast Accord and why it is authorised in the EU

What is Apremilast Accord and what is it used for?

Apremilast Accord is a medicine used to treat adults with:

- moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin). It is used in patients who have not responded to or cannot use other systemic (affecting the whole body) treatments for psoriasis, such as ciclosporin, methotrexate or PUVA (psoralen ultraviolet A). PUVA is a type of treatment where the patient receives a medicine containing a compound called a 'psoralen' before being exposed to ultraviolet light;
- active psoriatic arthritis (inflammation of the joints associated with psoriasis) in patients who cannot take or who have not responded well enough to other treatments called disease-modifying antirheumatic drugs (DMARDs). Apremilast Accord may be used alone or combined with other DMARDs;
- ulcers in the mouth caused by Behçet's disease, an inflammatory disease that may affect many parts of the body.

Apremilast Accord is a 'generic medicine'. This means that Apremilast Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Apremilast Accord is Otezla. For more information on generic medicines, see the question-and-answer document here.

Apremilast Accord contains the active substance apremilast.

How is Apremilast Accord used?

Apremilast Accord can only be obtained with a prescription and treatment should only be started by a doctor experienced in the diagnosis and treatment of psoriasis, psoriatic arthritis or Behçet's disease.

The medicine is available as tablets. Treatment begins with a lower dose taken once daily on the first day, and then the dose is gradually increased over a week to the recommended dose, which is taken twice daily. Lower doses should be given to patients with severe impairment of kidney function. Response to treatment should be evaluated regularly and use of Apremilast Accord should be reconsidered if there is no improvement after six months.

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

How does Apremilast Accord work?

The active substance in the medicine, apremilast, blocks the action of an enzyme inside cells called phosphodiesterase 4 (PDE4). This enzyme plays a role in triggering the production of messenger molecules in the immune system (the body's natural defences) called cytokines, which are involved in the inflammation and other processes that cause psoriasis, psoriatic arthritis and Behçet's disease. By blocking PDE4, apremilast reduces the level of these cytokines in the body, and so reduces the inflammation and other symptoms of psoriasis, psoriatic arthritis and Behçet's disease.

How has Apremilast Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Otezla, and do not need to be repeated for Apremilast Accord.

As for every medicine, the company provided studies on the quality of Apremilast Accord. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Apremilast Accord?

Because Apremilast Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Apremilast Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Apremilast Accord has been shown to have comparable quality and to be bioequivalent to Otezla. Therefore, the Agency's view was that, as for Otezla, the benefits of Apremilast Accord 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 Apremilast Accord?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Apremilast Accord have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Otezla also apply to Apremilast Accord where appropriate.

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

Other information about Apremilast Accord

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

Further information on Apremilast Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/apremilast-accord

Information on the reference medicine can also be found on the Agency’s website.

This overview was last updated in 04-2024.