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Posaconazole Accord (*posaconazole*)

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

What is Posaconazole Accord and what is it used for?

Posaconazole Accord is an antifungal medicine used to treat adults with the following fungal diseases, when treatments with other antifungal medicines (amphotericin B, itraconazole or fluconazole) cannot be tolerated or have failed:

- invasive aspergillosis (fungal infection caused by *Aspergillus*),
- fusariosis (fungal infection caused by *Fusarium*),
- chromoblastomycosis and mycetoma (long-term fungal infections of the skin or the tissue just below the skin, usually caused by fungal spores infecting wounds due to thorns or splinters),
- coccidioidomycosis (fungal infection of the lungs caused by breathing in spores).

Posaconazole Accord is also used to prevent invasive fungal infections in patients whose immune system is weakened because of treatments they are receiving for blood or bone marrow cancers or medicines used in haematopoietic stem cell transplantation (a procedure where the patient's bone marrow is replaced by stem cells from a donor to form new bone marrow).

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

How is Posaconazole Accord used?

Posaconazole Accord can only be obtained with a prescription and treatment should be started by a doctor who has experience in managing fungal infections or in treating patients at high risk of invasive fungal infections.

Posaconazole Accord is available as gastro-resistant tablets (100 mg). Gastro-resistant means that the tablets pass through the stomach without being broken down until they reach the intestine.

The recommended dose is 300 mg twice a day on the first day followed by 300 mg once a day thereafter; the duration of treatment depends on the severity of the disease and the patient's response.

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

How does Posaconazole Accord work?

The active substance in Posaconazole Accord, posaconazole, is an antifungal medicine that belongs to the triazole group. It works by preventing the formation of ergosterol, which is an important part of fungal cell walls. Without ergosterol, the fungus dies or is prevented from spreading. The list of fungi Posaconazole Accord is active against can be found in the summary of product characteristics.

How has Posaconazole 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, Noxafil, and do not need to be repeated for Posaconazole Accord.

As for every medicine, the company provided studies on the quality of Posaconazole Accord. The company also carried out studies 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 Posaconazole Accord?

Because Posaconazole 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 Posaconazole Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Posaconazole Accord has been shown to have comparable quality and to be bioequivalent to Noxafil. Therefore, the Agency's view was that, as for Noxafil, the benefit of Posaconazole Accord outweighs the identified risk and it can be authorised for use in the EU.

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

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

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

Other information about Posaconazole Accord

Posaconazole Accord received a marketing authorisation valid throughout the EU on 25 July 2019.

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

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

This overview was last updated in 08-2019.