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Posaconazole AHCL (*posaconazole*)

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

What is Posaconazole AHCL and what is it used for?

Posaconazole AHCL 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 AHCL is also used as a first-line treatment for 'thrush', a fungal infection of the mouth and throat due to *Candida*. It is used in patients whose infection is severe or in patients with weakened immune systems, when medicines applied topically (directly on the thrush) are unlikely to work.

Posaconazole AHCL 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 AHCL contains the active substance posaconazole and is a 'generic medicine'. This means that Posaconazole AHCL 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 AHCL used?

Posaconazole AHCL 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 AHCL is available as an oral suspension (40 mg/ml) which is taken with a meal or nutritional supplement.

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For the treatment of fungal infections, with the exception of thrush, Posaconazole AHCL is taken at a dose of 400 mg (10 ml) twice a day, or 200 mg (5 ml) four times a day in patients who are not eating. The duration of treatment depends on the severity of the disease and the patient's response. For thrush, Posaconazole AHCL is taken as 200 mg (5 ml) on the first day followed by 100 mg (2.5 ml) once a day for the following 13 days. For the prevention of invasive fungal infections, Posaconazole AHCL is taken at a dose of 200 mg (5 ml) three times a day. The duration of treatment depends on the patient's condition.

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

How does Posaconazole AHCL work?

The active substance in Posaconazole AHCL, 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 is active against can be found in the summary of product characteristics.

How has Posaconazole AHCL 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 AHCL.

As for every medicine, the company provided studies on the quality of Posaconazole AHCL. 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 Posaconazole AHCL?

Because Posaconazole AHCL 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 AHCL authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Posaconazole AHCL 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 AHCL 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 AHCL?

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

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

Other information about Posaconazole AHCL

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

Further information on Poxaconazole AHCL can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/posaconazole-ahcl.

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

This overview was last updated in 07-2019.