EMA/831772/2015
EMEA/H/C/002669

EPAR summary for the public

Voriconazole Accord

voriconazole

This is a summary of the European public assessment report (EPAR) for Voriconazole Accord. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Voriconazole Accord.

For practical information about using Voriconazole Accord, patients should read the package leaflet or contact their doctor or pharmacist.

What is Voriconazole Accord and what is it used for?

Voriconazole Accord is an antifungal medicine that contains the active substance voriconazole. It is used for the treatment of adults and children over the age of two years with:

- invasive aspergillosis (a type of fungal infection due to *Aspergillus*);
- candidaemia (another type of fungal infection due to *Candida*) in non-neutropenic patients (patients with a normal white blood cell count);
- serious invasive *Candida* infections when the fungus is resistant to fluconazole (another antifungal medicine);
- serious fungal infections caused by *Scedosporium* or *Fusarium* (two different types of fungus).

When used for treating fungal infections, Voriconazole Accord is intended mainly for patients with worsening, possibly life-threatening, fungal infections.

Voriconazole Accord is also used to prevent fungal infections in patients who have had haematopoietic (blood) stem-cell transplantation (a transplant of a type of stem cells that can develop into blood cells) and are at high risk of infection.

Voriconazole Accord is a 'generic medicine'. This means that Voriconazole Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Vfend. For more information on generic medicines, see the question-and-answer document here.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How is Voriconazole Accord used?

Voriconazole Accord is available as tablets (50 mg or 200 mg). It is given twice a day. The dose of Voriconazole Accord depends on the weight of the patient. Patients need to receive an initial higher dose (loading dose) on the first day of treatment. The aim of the loading dose is to attain effective blood levels quickly. The loading dose is then followed by a maintenance dose that can be adjusted according to the patient's response. The dose may be increased or decreased according to how the patient responds.

The tablets are to be taken at least one hour before or after a meal. For full information, see the package leaflet. The medicine can only be obtained with a prescription.

How does Voriconazole Accord work?

The active substance in Voriconazole Accord, voriconazole, 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 membranes. Without ergosterol, the fungus is killed or prevented from spreading. The list of fungi against which Voriconazole Accord is active can be found in the summary of product characteristics (also part of the EPAR).

How has Voriconazole Accord been studied?

Because Voriconazole Accord is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Vfend. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Voriconazole Accord?

Because Voriconazole 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 Voriconazole Accord approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Voriconazole Accord has been shown to have comparable quality and to be bioequivalent to Vfend. Therefore, the CHMP's view was that, as for Vfend, the benefit outweighs the identified risks. The Committee recommended that Voriconazole Accord be approved for use in the EU.

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

A risk management plan has been developed to ensure that Voriconazole Accord is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Voriconazole Accord, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Voriconazole Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Voriconazole Accord on 16 May 2013.

The full EPAR for Voriconazole Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Voriconazole Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 12-2015.