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EPAR summary for the public

Voriconazole Hikma

voriconazole

This is a summary of the European public assessment report (EPAR) for Voriconazole Hikma. 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 Hikma.

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

What is Voriconazole Hikma and what is it used for?

Voriconazole Hikma is an antifungal medicine used for the treatment of adults and children over the age of two years who have the following infections caused by a fungus:

- invasive aspergillosis (a type of fungal infection due to *Aspergillus*);
- candidaemia (a type of fungal infection due to *Candida*) in patients with a normal white blood cell count;
- other 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 Hikma is intended mainly for patients with infections that are worsening and possibly life-threatening.

Voriconazole Hikma 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 Hikma contains the active substance voriconazole. It is a 'generic medicine'. This means that Voriconazole Hikma is similar to a 'reference medicine' already authorised in the European Union

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(EU) called Vfend. For more information on generic medicines, see the question-and-answer document here.

How is Voriconazole Hikma used?

Voriconazole Hikma is available as a powder to be made up into a solution for infusion (drip) into a vein. It is given twice a day. The dose of Voriconazole Hikma depends on the weight of the patient.

Patients need to receive an initial higher dose (loading dose) on the first day. 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.

Both the loading and the maintenance doses are given by infusion, but once patients improve prescribers should consider switching patients to a voriconazole medicine that can be given by mouth.

The medicine can only be obtained with a prescription.

How does Voriconazole Hikma work?

The active substance in Voriconazole Hikma, voriconazole, belongs to the 'triazole' class of antifungal medicines. It works by disrupting the formation of ergosterol, which is an important part of fungal cell membranes. Without ergosterol, the fungus cannot spread or dies. The list of fungi against which Voriconazole Hikma is active can be found in the summary of product characteristics (also part of the EPAR).

How has Voriconazole Hikma been studied?

As for every medicine, the company provided studies on the quality of voriconazole. There was no need for 'bioequivalence' studies to investigate whether voriconazole is absorbed similarly to the reference medicine, Vfend, to produce the same level of the active substance in the blood. This is because voriconazole is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Voriconazole Hikma?

Because Voriconazole Hikma is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Voriconazole Hikma approved?

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

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

A risk management plan has been developed to ensure that Voriconazole Hikma 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 Hikma, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Voriconazole Hikma

The European Commission granted a marketing authorisation valid throughout the European Union for Voriconazole Hikma on 27 May 2015.

The full EPAR and risk management plan summary for Voriconazole Hikma 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 Hikma, 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 01-2017.