Summary Public Assessment Report

Generics

Voriconazol Fresenius Kabi 200 mg powder for solution for infusion

(Voriconazole)

NL/H/3248/001/DC

Date: 16 March 2016

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Active substance: voriconazole

This is a summary of the public assessment report (PAR) for Voriconazol Fresenius Kabi 200 mg powder for solution for infusion. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Voriconazol Fresenius Kabi.

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

What is Voriconazol Fresenius Kabi and what is it used for?
Voriconazol Fresenius Kabi 200 mg powder for solution for infusion is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Vfend 200 mg powder for solution for infusion.

Voriconazole Fresenius Kabi is intended for the treatment of patients with worsening, possibly life-threatening, fungal infections. It is used for the treatment of patients (over the age of 2) with the following infections:

- Invasive aspergillosis (a fungal infection due to *Aspergillus* sp.)
- Candidaemia (a fungal infection due to *Candida* sp., in patients without abnormally low white blood cells count (non-neutropenic patients)
- Serious invasive infections caused by *Candida* sp. when the fungus is resistant to another antifungal medicine, fluconazole
- Serious fungal infections caused by two species of fungi, *Scedosporium* and *Fusarium*.

The product is also used for prevention of fungal infections in high risk bone marrow transplant (HSCT) recipients.

How does this medicine work?
Voriconazol Fresenius Kabi is an antifungal medicine. The product contains the active substance voriconazole. It works by blocking the formation of an important fungal sterol called ergosterol. Without ergosterol, the fungus is killed or prevented from spreading.

How is this medicine used?
The pharmaceutical form of Voriconazol Fresenius Kabi is powder for solution and the route of administration is intravenously. The medicine can only be obtained with a prescription and should only be used under the supervision of a doctor.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
No additional studies were needed as Voriconazol Fresenius Kabi is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Vfend.

What are the possible side effects of this medicine?
Because Voriconazol Fresenius Kabi is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality as the reference medicine. Therefore, the Medicines Evaluation Board of the

Netherlands decided that, as for the reference medicine, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Voriconazol Fresenius Kabi, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored continuously as well.

Additional risk minimisation measures are required relating to phototoxicity, hepatotoxicity and squamous cell carcinoma. These have been laid down in line with the reference product. It concerns the following additional risk minimisation measures:

- Health Care Professional Checklist for phototoxicity, Squamous Cell Carcinoma and hepatic toxicity
- Health Care Professional Question and Answer Brochure for phototoxicity, Squamous Cell Carcinoma and hepatic toxicity
- Patient Alert Card for Squamous Cell Carcinoma.

Other information about this medicine
In the Netherlands, the marketing authorisation for Voriconazol Fresenius Kabi was granted on 3 November 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Voriconazol Fresenius Kabi, read the package leaflet (http://mri.medagencies.org/download/NL_H_3248_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in March 2016.