26 March 2015
EMA/CHMP/189813/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Voriconazole Hospira

voriconazole

On 26 March 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Voriconazole Hospira, intended for the treatment of fungal infections.

The applicant for this medicinal product is Hospira UK Limited.

Voriconazole Hospira will be available as a powder (200 mg) to be made up into a solution for infusion. The active substance of Voriconazole Hospira is voriconazole, a broad spectrum, triazole antifungal agent (ATC code: J02AC03) that acts by inhibiting the enzyme 14-α-sterol demethylase, resulting in depletion of ergosterol and accumulation of 14- α-methylated sterols which are thought to contribute to the disruption of fungal cell membrane structure and function, thereby inhibiting fungal growth.

Voriconazole Hospira is a generic of Vfend, which has been authorised in the EU since 19 March 2002.

The full indication is: "Voriconazole is a broad spectrum, triazole antifungal agent and is indicated in adults and children aged 2 years and above as follows:

- Treatment of invasive aspergillosis.
- Treatment of candidaemia in non-neutropenic patients.
- Treatment of fluconazole-resistant serious invasive *Candida* infections (including *C. krusei*).
- Treatment of serious fungal infections caused by *Scedosporium* spp. and *Fusarium* spp.

Voriconazole should be administered primarily to patients with progressive, possibly life-threatening infections."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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