21 March 2013
EMA/151315/2013
Committee for medicinal products for human use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Voriconazole Accord

VORICONAZOLE

On 21 March 2013 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 Accord, 50 mg and 200 mg film-coated tablets intended for the treatment of invasive aspergillosis, treatment of candidemia in non-neutropenic patients, treatment of fluconazole-resistant serious invasive *Candida* infections (including *C. krusei*) and treatment of serious fungal infections caused by *Scedosporium spp*. and *Fusarium spp*. The applicant for this medicinal product is Accord Healthcare Limited.

The active substance of Voriconazole Accord is voriconazole, an antimycotic for systemic use J02A C03. Voriconazole, is a broad spectrum, triazole antifungal agent. The primary mode of action of voriconazole is the inhibition of fungal cytochrome P-450-mediated 14 alpha-lanosterol demethylation, an essential step in fungal ergosterol biosynthesis. The accumulation of 14 alpha-methyl sterols correlates with the subsequent loss of ergosterol in the fungal cell membrane and may be responsible for the antifungal activity of voriconazole.

*Voriconazole Accord* is a generic of VFEND, which has been authorised in the EU since 19 March 2002. Studies have demonstrated the satisfactory quality of Voriconazole Accord, and its bioequivalence with the reference product VFEND. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan *Voriconazole Accord* will be implemented as part of the marketing authorisation.

The approved indication is: “Treatment of invasive aspergillosis, treatment of candidemia in non-neutropenic patients, treatment of fluconazole-resistant serious invasive *Candida* infections (including *C. krusei*), and treatment of serious fungal infections caused by *Scedosporium* spp. and *Fusarium* spp”.

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

[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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will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for *Voriconazole Accord* and therefore recommends the granting of the marketing authorisation.