EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 December 2015
EMA/CHMP/843681/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Caspofungin Accord

caspofungin

On 17 December 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 Caspofungin Accord, intended for the treatment of fungal infections. The applicant for this medicinal product is Accord Healthcare Ltd.

Caspofungin Accord will be available as 50 mg and 70 mg powder for concentrate for solution for infusion. The active substance of Caspofungin Accord is caspofungin, an antimycotic for systemic use (ATC code: J02AX04). Caspofungin inhibits the synthesis of beta (1,3)-D-glucan, an essential component of the cell wall of many filamentous fungi and yeast.

Caspofungin Accord is a generic of Cancidas, which has been authorised in the EU since 24 October 2001. Studies have demonstrated the satisfactory quality of Caspofungin Accord. Since Caspofungin Accord is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Cancidas was not required. A question and answer document on generic medicines can be found here.

The full indication is:

- Treatment of invasive candidiasis in adult or paediatric patients.
- Treatment of invasive aspergillosis in adult or paediatric patients who are refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and/or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.
- Empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropaenic adult or paediatric patients.

It is proposed that Caspofungin Accord be initiated by physicians experienced in the the management of invasive fungal infections.

Detailed recommendations for the use of this product will be described in the summary of product

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

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 granted by the European Commission.