European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 21 February 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
MYCAMINE

International Nonproprietary Name (INN): ***micafungin***

On 21 February 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Mycamine, 50 mg & 100 mg, powder for solution for infusion, intended for the treatment and prophylaxis of Candida infection. The applicant for this medicinal product is Astellas Pharma GmbH.

The active substance of Mycamine is micafungin, an antimycotic for systemic use (ATC Code: (J02AX05)). Micafungin sodium is a semi-synthetic novel drug substance with antifungal activity which selectively inhibits the synthesis of 1,3-β D-glucan.

The benefits with Mycamine are its clinical and microbiological cure and prophylaxis of Candida infection. The most common side effects are vomiting, nausea and diarrhoea and elevated liver enzymes.

A pharmacovigilance plan for Mycamine, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:

"Adults, adolescents ≥ 16 years of age and elderly:
- Treatment of invasive candidiasis.
- Treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate.
- Prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells / µl) for 10 or more days.

Children (including neonates) and adolescents < 16 years of age:
- Treatment of invasive candidiasis.
- Prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells / µl) for 10 or more days.

The decision to use Mycamine should take into account a potential risk for the development of liver tumours (see SPC section 4.4). Mycamine should therefore only be used if other antifungals are not appropriate."

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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Treatment with Mycamine should be initiated by a physician experienced in the management of fungal infections.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and 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 that there is a favourable benefit to risk balance for Mycamine and therefore recommends the granting of the marketing authorisation.