23 July 2015
EMA/CHMP/470149/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cresemba

isavuconazole

On 23 July 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 Cresemba, intended for the treatment of invasive aspergillosis and mucormycosis. Cresemba was designated as an orphan medicinal product on 4 July 2014 for invasive aspergillosis and 4 June 2014 for mucormycosis. The applicant for this medicinal product is Basilea Medical Ltd.

Cresemba will be available as 100 mg capsules and as a 200 mg powder for concentrate for solution for infusion. The active substance of Cresemba is isavuconazole, an antifungal triazole (ATC code: J02). It has a fungicidal effect by blocking the synthesis of ergosterol, a key component of the fungal cell membrane, through the inhibition of the enzyme lanosterol 14 alpha demethylase.

Cresemba, through its antifungal action, has been shown to be effective at treating invasive aspergillosis and mucormycosis, which are life-threatening diseases with limited treatment options. The most common side effects are elevated liver chemistry tests, nausea, vomiting, dyspnoea, abdominal pain, diarrhoea, injection site reactions, headache, hypokalaemia and rash.

The full indication is:

"Cresemba is indicated in adults for the treatment of

- invasive aspergillosis
- mucormycosis in patients for whom amphotericin B is inappropriate (see sections 4.4 and 5.1)

Consideration should be given to official guidance on the appropriate use of antifungal agents."

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 granted by the European Commission.

[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