EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2024
EMA/298353/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Cresemba

isavuconazole

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Cresemba. The marketing authorisation holder for this medicinal product is Basilea Pharmaceutica Deutschland GmbH.

The CHMP adopted an extension to the existing indication for Cresemba (powder for concentrate for solution for infusion) to include treatment of patients over 1 year of age. For information, the full indication for this formulation will be as follows:[2]

> Cresemba is indicated in ~~adults~~ **patients from 1 year of age and older** 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.

The CHMP also adopted a new pharmaceutical formulation (40 mg hard capsules) for Cresemba associated with the extended indication. The full indication for Cresemba hard capsules will be as follows:[2]

> Cresemba **hard capsules** ~~is~~ **are** indicated in adults **and in paediatric patients from 6 years of age** 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.
>
> **Cresemba 40 mg hard capsules are intended to be used for paediatric patients.**

[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
[2] New text in bold, removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.