



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Cresemba

## isavuconazole

This is a summary of the European public assessment report (EPAR) for Cresemba. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Cresemba.

For practical information about using Cresemba, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Cresemba and what is it used for?

Cresemba is an antifungal medicine used to treat adults with either of two life-threatening fungal infections: invasive aspergillosis and mucormycosis. For mucormycosis, Cresemba is used when amphotericin B is inappropriate.

Because the number of patients with these diseases is low, they are considered 'rare', and Cresemba was designated an 'orphan medicine' (a medicine used in rare diseases) on 4 June 2014 (for mucormycosis) and 4 July 2014 (for aspergillosis).

Cresemba contains the active substance isavuconazole.

### How is Cresemba used?

Cresemba is available as a powder used to make a solution for infusion (drip) into a vein and as capsules to be taken by mouth.

The dosage for the infusions and capsules are the same: 200 mg every 8 hours for the first 48 hours, followed by a 200-mg maintenance dose once a day. Duration of treatment depends on how the patient responds to treatment.



It is possible to switch between the infusion and the oral capsule if needed. The medicine can only be obtained with a prescription.

## **How does Cresemba work?**

The active substance in Cresemba, isavuconazole, belongs to the 'triazole' class of antifungal medicines. It works by disrupting the formation of ergosterol, an important component of fungal cell membranes. Without a functional cell membrane, the fungus is killed or prevented from spreading.

## **What benefits of Cresemba have been shown in studies?**

Studies show that survival following treatment with Cresemba is similar to that seen with other treatments.

In a main study of 516 patients with invasive aspergillosis, the mortality rate at 42 days was similar in patients treated with Cresemba (19%) and those treated with another antifungal medicine voriconazole (20%).

Another study included 146 patients, among which 37 patients had mucormycosis and were treated with Cresemba; in patients with mucormycosis the mortality rate after 84 days was 43%, which is similar to rates seen in the published literature for standard treatments with amphotericin-B. In addition, Cresemba has the advantage that it can be used in patients with reduced kidney function.

## **What are the risks associated with Cresemba?**

The most common side effects with Cresemba (seen in more than 10% of patient studied) were: abnormal liver tests, nausea, vomiting, difficulty breathing, abdominal pain, diarrhea, injection site reactions, headache, low blood potassium and skin rash. For the full list of all side effects reported with Cresemba, see the package leaflet.

Cresemba must not be used in patients who are taking any of the following:

- ketoconazole (an antifungal)
- high-dose ritonavir (an HIV medicine)
- certain medicines that enhance the breakdown of isavuconazole in the body (strong inducers of CYP3A4/5, see the package leaflet).

It must also not be used in patients with familial short QT syndrome, a heart rhythm problem.

## **Why is Cresemba approved?**

Invasive aspergillosis and mucormycosis are life-threatening infections associated with high mortality. In studies, Cresemba's effect was comparable to that of voriconazole in treating invasive aspergillosis. Although amphotericin B is the first line treatment for mucormycosis, there is a need for alternative treatments and Cresemba will benefit patients for whom amphotericin B is not appropriate. Regarding safety, Cresemba was relatively well tolerated.

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Cresemba's benefits are greater than its risks and recommended that it be approved for use in the EU.

## What measures are being taken to ensure the safe and effective use of Cresemba?

A risk management plan has been developed to ensure that Cresemba is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Cresemba, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

## Other information about Cresemba

<The European Commission granted a marketing authorisation valid throughout the European Union for <X> on < date of issue of the Marketing Authorisation>.>

The full EPAR and risk management plan summary for Cresemba can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Cresemba, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Cresemba can be found on the Agency's website:

[ema.europa.eu/Find medicine/Human medicines/Rare disease designation](http://ema.europa.eu/Find%20medicine/Human%20medicines/Rare%20disease%20designation) (invasive aspergillosis)

[ema.europa.eu/Find medicine/Human medicines/Rare disease designation](http://ema.europa.eu/Find%20medicine/Human%20medicines/Rare%20disease%20designation) (mucormycosis)

This summary was last updated in 09-2015.