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Cresemba (*isavuconazole*)

An overview of Cresemba and why it is authorised in the EU

What is Cresemba and what is it used for?

Cresemba is an antifungal medicine used to treat adults and children aged 1 year and older with invasive aspergillosis or mucormycosis (infections caused by fungi). For mucormycosis, Cresemba is used when another medicine, amphotericin B, is not suitable.

Invasive aspergillosis and mucormycosis are rare, and Cresemba was designated an 'orphan medicine' (a medicine used in rare diseases). Further information on the orphan designations can be found on the EMA website (mucormycosis: 4 June 2014; invasive aspergillosis: 4 July 2014).

Cresemba contains the active substance isavuconazole.

How is Cresemba used?

Cresemba is available as a powder to make a solution for infusion (drip) given into a vein and as capsules to be taken by mouth. It is given once every 8 hours for the first 48 hours and then once a day. For children the dose and form depend on their bodyweight and age. The duration of treatment depends on how the patient responds to Cresemba.

For adults and children aged 6 years and older and weighing at least 16 kg, it is possible to switch between the infusion and the capsules, if needed.

Cresemba can only be obtained with a prescription. It should be used according to official recommendations on the appropriate use of antifungal medicines. For more information about using Cresemba, see the package leaflet or contact your doctor or pharmacist.

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 the fungal cell membranes (outer layers). Without a functional cell membrane, the fungus dies or cannot spread.

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What benefits of Cresemba have been shown in studies?

Studies have shown that survival of infected patients following treatment with Cresemba is similar to that seen with other antifungal treatments.

In a main study involving 516 adults with invasive aspergillosis, the proportion of people who died at 42 days was similar for those treated with Cresemba (19%) and those treated with another antifungal medicine called voriconazole (20%).

Another study involved 146 adults, 37 of whom had mucormycosis and were treated with Cresemba. Of these 37 patients, 43% died after 84 days, which is similar to rates seen in the published literature for standard treatments with amphotericin-B; Cresemba has the advantage that it can be used in patients with reduced kidney function.

The company also provided data from two studies involving a total of 77 children aged 1 to 18 years, 31 of whom had invasive aspergillosis or mucormycosis, and who were treated with Cresemba. The results showed that Cresemba behaves in the body in the same way in children as in adults.

What are the risks associated with Cresemba?

For the full list of side effects and restrictions with Cresemba, see the package leaflet.

The most common side effects with Cresemba in adults (which may affect up to 1 in 10 people) include abnormal liver tests, nausea (feeling sick), vomiting, dyspnoea (difficulty breathing), abdominal (belly) pain, diarrhoea, injection site reactions, headache, hypokalaemia (low blood potassium) and skin rash.

The side effects with Cresemba when used in children are similar to those seen in adults.

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 increase the breakdown of isavuconazole in the body.

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

Why is Cresemba authorised in the EU?

Invasive aspergillosis and mucormycosis are life-threatening infections associated with high rates of death. At the time of authorisation there were few treatment options for adults with these infections, and even fewer for children.

In studies, Cresemba's effect was comparable to that of voriconazole in treating invasive aspergillosis. In the treatment of mucormycosis, the European Medicines Agency considered that Cresemba would benefit patients for whom amphotericin B, which is the first-line treatment for this infection, is not suitable. Studies in children show that Cresemba behaves in the same way as in adults. The medicine is therefore expected to also be effective in children aged 1 year and above with invasive aspergillosis or mucormycosis. Regarding safety, Cresemba was relatively well tolerated.

The Agency therefore decided that Cresemba's benefits are greater than its risks and that it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Cresemba have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Cresemba are continuously monitored. Suspected side effects reported with Cresemba are carefully evaluated and any necessary action taken to protect patients.

Other information about Cresemba

Cresemba received a marketing authorisation valid throughout the EU on 15 October 2015.

Further information on Cresemba can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cresemba.

This overview was last updated in 07-2024.