



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Cancidas

caspofungin

This is a summary of the European public assessment report (EPAR) for Cancidas. 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 Cancidas.

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

What is Cancidas and what is it used for?

Cancidas is an antifungal medicine used to treat the following fungal infections in adults and children:

- invasive candidiasis (an infection caused by *Candida*). 'Invasive' means that the infection has spread into the blood;
- invasive aspergillosis (an infection caused by *Aspergillus*) when the patient does not respond to or does not tolerate amphotericin B or itraconazole (other antifungal medicines);
- suspected fungal infections (such as due to *Candida* or *Aspergillus*) when the patient is feverish and has low white blood cell counts. This is known as 'empirical treatment', which means that the doctor starts treatment based on an observation of the patient before confirming that the patient has the infection.

Cancidas contains the active substance caspofungin

How is Cancidas used?

Cancidas treatment should be started by a doctor who has experience in the management of invasive fungal infections.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555

Send a question via our website www.ema.europa.eu/contact

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Cancidas is a powder that is made up into a solution for infusion (drip) into a vein. It is given once a day by infusion lasting about one hour. In adults, treatment starts with a 70 mg on the first day, followed by a daily dose of 50 mg, or 70 mg if the patient weighs more than 80 kg. A lower dose may be necessary in adults who have moderate problems with their liver.

In patients between 12 months and 17 years of age, the dose is calculated using the child's height and weight. Cancidas should be used with care in children below 12 months of age, because it has not been studied sufficiently in this age group.

Treatment is continued for up to two weeks after the infection has been cured. The medicine can only be obtained with a prescription.

How does Cancidas work?

The active substance in Cancidas, caspofungin, belongs to a group of antifungal medicines known as 'echinocandins'. It works by interfering with the production of a component of the fungal cell wall called 'glucan polysaccharide', which is necessary for the fungus to continue living and growing. Fungal cells treated with Cancidas have incomplete or defective cell walls, making them fragile and unable to grow. The list of fungi against which Cancidas is active can be found in the summary of product characteristics (also part of the EPAR).

What benefits of Cancidas have been shown in studies?

Studies show that Cancidas treatment can lead to favourable responses in patients with fungal infections, including improvement of symptoms and the clearing of fungus from patient's body.

In a study of 239 adults with invasive candidiasis, 73% of the adults treated with Cancidas who could be assessed had a favourable response (80 out of 109), compared with 62% of the adults treated with amphotericin B (71 out of 115).

In an invasive aspergillosis study involving 69 adults, 41% had a favourable response to Cancidas at the end of the study (26 out of 63). Of the adults who did not respond to other treatments, 36% responded to Cancidas (19 out of 53). Of those who did not tolerate other treatments, 70% responded to Cancidas (7 out of 10).

Similar responses were seen in a study in 49 children and adolescents with either invasive candidiasis or invasive aspergillosis: 50% of those with invasive candidiasis (5 out of 10) and 81% of those with invasive aspergillosis (30 out of 37) responded to Cancidas.

Finally, in 2 studies of patients with suspected fungal infection who were treated empirically, Cancidas was as effective as amphotericin B. In one of studies involving around 1,000 adults, 34% of patients had a favourable response with either Cancidas or amphotericin B. Similar results were seen in the second study, which involved 82 children aged between two and 17 years.

What are the risks associated with Cancidas?

The most common side effects with Cancidas in adults (which may affect up to 1 in 100 people) are reduced levels of haemoglobin or red blood cells, reduced white blood cell count, low levels of potassium in the blood, headache, inflammation of the veins, shortness of breath, nausea, diarrhoea, vomiting, raised levels of liver enzymes and bilirubin (which may indicate liver problems), rash, itching, redness of skin, excessive sweating, joint pain, fever, chills, itching at injection site, and reduced levels of albumin, a protein in the blood.

The most common side effect in children is fever and this occurs in more than 1 patient in 10. For the full list of all side effects reported with Cancidas in adults and children, see the Package Leaflet.

Why is Cancidas approved?

The CHMP decided that evidence from the studies with Cancidas show that the medicines benefits are greater than its risks for the treatment of invasive candidiasis or aspergillosis, and for empirical therapy for presumed fungal infections, in adults or children. The Committee therefore recommended that Cancidas be given marketing authorisation.

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

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

Other information about Cancidas

The European Commission granted a marketing authorisation valid throughout the European Union for Caspofungin MSD on 24 October 2001. The name of the medicine was changed to Cancidas on 9 April 2003.

The full EPAR for Cancidas can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Cancidas, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2016.