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EPAR summary for the public

Caspofungin Accord

caspofungin

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

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

What is Caspofungin Accord and what is it used for?

Caspofungin Accord is an antifungal medicine used to treat adults, adolescents and children with:

- invasive candidiasis (a type of fungal infection due to *Candida*);
- invasive aspergillosis (another type of fungal infection due to *Aspergillus*) when the infection does not respond to or the patient does not tolerate amphotericin B or itraconazole (other antifungal medicines);
- suspected fungal infections (such as due to *Candida* or *Aspergillus*) when the patient is febrile (feverish) and neutropenic (has low levels of white blood cells).

Caspofungin Accord is a powder that is made up into a solution for infusion (drip) into a vein. It contains the active substance caspofungin.

Caspofungin Accord is a 'generic medicine'. This means that Caspofungin Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Cancidas. For more information on generic medicines, see the question-and-answer document here.

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How is Caspofungin Accord used?

Caspofungin Accord can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of invasive fungal infections. Caspofungin Accord must be made up into a concentrated solution and then diluted before use, using a diluent that does not contain glucose.

It is given once a day by slow infusion lasting about one hour. In adults, treatment begins with a 70-mg starting dose, followed by a daily dose of 50 mg, or of 70 mg if the patient weighs more than 80 kg. A lower dose is given to adults who have moderate problems with their liver.

In patients between 12 months and 17 years of age, the dose depends on body surface area (calculated using the patient's height and weight). Caspofungin Accord should be used with caution 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.

How does Caspofungin Accord work?

The active substance in Caspofungin Accord, 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 survive and grow. Fungal cells treated with Caspofungin Accord have incomplete or defective cell walls, making them fragile, unable to grow and causing their death. The list of fungi against which Caspofungin Accord is active can be found in the summary of product characteristics (also part of the EPAR).

How has Caspofungin Accord been studied?

The company provided data from the published literature on caspofungin. No additional studies in humans were needed as Caspofungin Accord is a generic medicine that is given by infusion and contains the same active substance as Cancidas.

What are the benefits and risks of Caspofungin Accord?

Because Caspofungin Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Caspofungin Accord approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Caspofungin Accord has been shown to be comparable to Cancidas. Therefore, the CHMP's view was that, as for Cancidas, the benefit outweighs the identified risk. The Committee recommended that Caspofungin Accord be approved for use in the EU.

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

A risk management plan has been developed to ensure that Caspofungin Accord 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 Caspofungin Accord, 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 Caspofungin Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Caspofungin Accord on 11 February 2016.

The full EPAR and risk management plan summary for Caspofungin Accord 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 Caspofungin Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 02-2016.