

# Summary Public Assessment Report

## Caspofungin Orion (caspofungin)

**SE/H/1543/01-02/DC**

# Summary Public Assessment Report

Caspofungin Orion  
(caspofungin)

Powder for concentrate for solution for infusion, 50 mg and 70 mg

This is a summary of the public assessment report (PAR) for Caspofungin Orion. It explains how Caspofungin Orion was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Caspofungin Orion.

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

## What is Caspofungin Orion and what is it used for?

Caspofungin Orion is a 'generic medicine'. This means that Caspofungin Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Cancidas.

Caspofungin Orion contains the active substance caspofungin. This belongs to a group of medicines called antifungals.

Caspofungin Orion is used to treat the following infections in children, adolescents and adults:

- serious fungal infections in your tissues or organs (called 'invasive candidiasis'). This infection is caused by fungal (yeast) cells called Candida. People who might get this type of infection include those who have just had an operation or those whose immune systems are weak. Fever and chills that do not respond to an antibiotic are the most common signs of this type of infection.
- fungal infections in your nose, nasal sinuses or lungs (called 'invasive aspergillosis') if other anti-fungal treatments have not worked or have caused side effects. This infection is caused by a mould called Aspergillus. People who might get this type of infection include those having chemotherapy, those who have had a transplant and those whose immune systems are weak.
- suspected fungal infections if you have a fever and a low white cell count that have not improved on treatment with an antibiotic. People who are at risk of getting a fungal infection include those who have just had an operation or those whose immune systems are weak.

## How does Caspofungin Orion work?

Caspofungin Orion makes fungal cells fragile and stops the fungus from growing properly. This stops the infection from spreading and gives the body's natural defences a chance to completely get rid of the infection.

## How is Caspofungin Orion used?

The pharmaceutical form of Caspofungin Orion is powder for concentrate for solution for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

### **What benefits of Caspofungin Orion have been shown in studies?**

No additional studies were needed as Caspofungin Orion is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Cancidas.

### **What are the possible side effects of Caspofungin Orion?**

Because Caspofungin Orion is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

### **Why is Caspofungin Orion approved?**

It was concluded that, in accordance with EU requirements, Caspofungin Orion has been shown to have comparable quality and to be similar to the reference medicine Cancidas. Therefore, the Medical Products Agency in Sweden decided that, as for Cancidas, the benefits are greater than its risks and recommended that it can be approved for use.

### **What measures are being taken to ensure the safe and effective use of Caspofungin Orion?**

A risk management plan has been developed to ensure that Caspofungin Orion 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 Orion, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

### **Other information about Caspofungin Orion**

The marketing authorisation for Caspofungin Orion was granted on 2017-01-30 in Sweden.

The full PAR for Caspofungin Orion can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Caspofungin Orion, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2017-02.