LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Kaspofungin Lorien
# (caspofungin (anhydrous), caspofungin acetate)

# SE/H/2434/001-002/DC

**This module reflects the scientific discussion for the approval of Kaspofungin Lorien. The Summary Public Assessment Report was written in (February 2017) by the previous RMS (NL) after initial procedure NL/H/3562/001-002/DC. RMS transfer from (NL) to SE was completed 07-09-2023.**

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**Summary Public Assessment Report**

**Generics**

# Caspofungine Regiomedica 50 mg and 70 mg, powder for concentrate for solution for infusion

**(caspofungin)**

**NL/H/3562/001-002/DC**

I. Date: 16 February 2017

**Summary Public Assessment Report**

**Generics**

Caspofungine Regiomedica 50 mg and 70 mg, powder for concentrate for solution for infusion

Active substance: caspofungin

This is a summary of the public assessment report (PAR) for Caspofungine Regiomedica. It explains how this medicine 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 Caspofungine Regiomedica.

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

**What is Caspofungine Regiomedica and what is it used for?**
Caspofungine Regiomedica is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Cancidas.

Caspofungin Regiomedica 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 Iitraconazole (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).

**How does this medicine work?**
The active substance in Caspofungin Regiomedica, 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 Regiomedica have incomplete or defective cell walls, making them fragile, unable to grow and causing their death.

**How is this medicine used?**
The pharmaceutical form of Caspofungine Regiomedica is a powder that is made up into a solution for infusion (drip) into a vein. Caspofungin Regiomedica 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 Regiomedica 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 Regiomedica 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.

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

**How has this medicine been studied?**
No additional studies in humans were needed as Caspofungin Regiomedica is a generic medicine that is given by infusion and contains the same active substance as Cancidas.

**What are the possible side effects of this medicine?**
Because Caspofungine Regiomedica is a generic medicine and its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

**Why is this medicine approved?**

It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be comparable to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Cancidas, the benefits are greater than its risk and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of this medicine?**
A risk management plan has been developed to ensure that this medicine 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 Caspofungine Regiomedica, 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 this medicine**
In the Netherlands, the marketing authorisation for Caspofungine Regiomedica was granted on 22 November 2016.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Caspofungine Regiomedica, read the package leaflet (http://mri.cts-mrp.eu/Human/Product/Details/48642) or contact your doctor or pharmacist.

This summary was last updated in February 2017.