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Summary of the risk management plan (RMP) for Caspofungin Accord (caspofungin acetate)

This is a summary of the risk management plan (RMP) for Caspofungin Accord , which details the measures to be taken in order to ensure that Caspofungin Accord is used as safely as possible. For more information on RMP summaries, see here.

This RMP summary should be read in conjunction with the EPAR summary and the product information for Caspofungin Accord , which can be found on Caspofungin Accord 's EPAR page.

Overview of disease epidemiology

Caspofungin Accord is an antifungal medicine used to treat adults, adolescents and children with fungal infections such as invasive candidiasis (a type of fungal infection due to the fungus Candida which has spread into the blood) and invasive aspergillosis (another type of fungal infection which has spread into the blood and which is due to Aspergillus).

Rates of death related to invasive fungal disease in Europe depend on the pathogen, geographical location and underlying patient characteristics, with rates ranging from 28 to 59% for invasive Candida infections and from 38 to 80% for invasive aspergillosis. More than 50% of invasive candidiasis cases are caused by Candida albicans according to European surveys. However, occurrence of invasive fungal diseases not related to Candida albicans appears to be increasing due to changes in treatment strategies and increased use of antifungal prevention.

Summary of treatment benefits

Caspofungin Accord contains the active substance caspofungin. Caspofungin Accord is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Candicas.

Because Caspofungin Accord is a generic medicine, its benefits and risks are taken as being the same as those of the reference medicine. The company provided data from the published literature on caspofungin. No additional studies were needed as Caspofungin Accord is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Candicas.

Unknowns relating to treatment benefits

Information on safety and efficacy is limited in patients over 65 years of age, patients with severe liver disease, patients treated for longer than 4 weeks, neonates and infants aged less than 12 months and patients with yeast (non-Candida) and moulds (non-Aspergillus).

Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergic reactions (Hypersensitivity reactions including histamine-mediated adverse reactions)	Hypersensitivity reactions such as rash, itching, feeling warm, swelling of face, lips or throat, difficulty breathing with or without wheezing (whistling sound produce during breathing) have been reported with caspofungin, the active substance of Caspofungin Accord.	Caspofungin Accord should not be used in patients allergic to caspofungin or any other ingredient of this medicine. In case of an allergic reaction, treatment with Caspofungin Accord may have to be stopped and appropriate treatment may have to be started. Patients should inform their doctor or nurse if they have the following side effects, as they may need an urgent medical treatment: rash, itching, feeling warm, swelling of face, lips or throat or difficulty breathing, difficulty breathing with wheezing or a rash that gets worse.
Liver injury (hepatotoxicity)	Side effects affecting the liver such as changes in some laboratory blood tests (including increased values of some liver tests) have been commonly reported (may affect up to 1 in 10 people) in adults and children. Other side effects such as a decreased flow of bile, enlarged liver, liver disorder and liver injury have also been reported (affecting up to 1 in 100 people).	Patients who have any liver problems should talk to their doctor, nurse or pharmacist before taking caspofungin. Patients who get any side effects, should talk to their doctor, pharmacist or nurse. Patients might need a different dose of caspofungin if they have had a liver problem.
Development of drug resistance (when the virus becomes resistant to treatment with the medicine)	Caspofungin resistance has been rarely observed in patients with fungal infections that occurred in nose, nasal sinuses or lungs (called 'invasive aspergillosis').	To avoid the occurrence of resistance, the recommended dosing and treatment duration should be followed. Caspofungin Accord should only be prescribed by a doctor experienced in the management of invasive fungal infections.
Drug interaction with rifampin and other medicines that could decrease the amount of caspofungin in the body	Certain medicines (such as the anti-infective rifampicin) can affect the way Caspofungin Accord works by decreasing the amount of caspofungin in the body.	When using Caspofungin Accord together with these medicines, a dose adjustment may be needed. Full guidance can be found in the prescribing information. It is important that patients tell their doctor, nurse or pharmacist if they are taking, have recently taken or might take rifampicin or other medicines.
Drug interaction	Ciclosporin may increase the amount	When using Caspofungin Accord together

Risk	What is known	Preventability
with ciclosporin	of caspofungin in the body and may cause liver problems.	with ciclosporin the patient's liver function should be monitored. Full guidance can be found in the prescribing information. It is important that patients tell their doctor, nurse or pharmacist if they are taking, have recently taken or might take ciclosporin.
Drug interaction with tacrolimus	Caspofungin can affect the way tacrolimus (a medicine used to help prevent organ transplant rejection or to suppress the immune system) works. Studies in healthy adult volunteers have shown that caspofungin reduces the blood levels of tacrolimus (through levels) by 26%.	When using Caspofungin Accord together with tacrolimus, the patient's blood levels should be monitored. Full guidance can be found in the prescribing information. It is important that patients tell their doctor, nurse or pharmacist if they are taking, have recently taken or might take tacrolimus.

Important potential risks

There are no important potential risks.

Missing information

Risk	What is known
Exposure during pregnancy or breastfeeding (lactation)	There are no or limited data regarding the use of caspofungin in pregnant women. Caspofungin Accord should only be used in pregnancy if the potential benefit justifies the potential risk to the unborn baby. It is not known whether caspofungin passes into human breastmilk. Women given Caspofungin Accord should not breastfeed. Women who are pregnant or breastfeeding or think they are pregnant should ask their doctor for advice before taking Caspofungin Accord.
Safety and efficacy in children below 3 months of age (Additional data on the safety and effectiveness in neonates and infants below 3 months of age)	There are limited data available on the use of caspofungin in children below 3 months of age. Limited data suggest that caspofungin at a reduced dose of 25 mg/m^2 daily in neonates and infants less than 3 months of age can be considered.

Summary of risk minimisation measures by safety concern

All medicines have a summary of product characteristics (SmPC) which provides physicians, pharmacists and other healthcare professionals with details on how to use the medicine, and also describes the risks and recommendations for minimising them. Information for patients is available in lay language in the package leaflet. The measures listed in these documents are known as 'routine risk minimisation measures'.

The SmPC and the package leaflet are part of the medicine's product information. The product information for Caspofungin Accord can be found on Caspofungin Accord's EPAR page.

Planned post-authorisation development plan

None.

Summary of changes to the risk management plan over time

Not applicable.

This summary was last updated in 01-2016.