Part VI: Summary of the risk management plan

Summary of risk management plan for CASPOFUNGIN STADA 50 mg, 70 mg powder for concentrate for solution for infusion (Caspofungin)

This is a summary of the risk management plan (RMP) for CASPOFUNGIN Stada. The RMP details important risks of CASPOFUNGIN Stada, how these risks can be minimised, and how more information will be obtained about CASPOFUNGIN Stada's risks and uncertainties (missing information).

CASPOFUNGIN Stada's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how CASPOFUNGIN Stada should be used.

I. The medicine and what it is used for

CASPOFUNGIN Stada is authorised for the:

- Treatment of invasive candidiasis in adult or paediatric patients.
- Treatment of invasive aspergillosis in adult or paediatric patients who are refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and/or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.
- Empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropaenic adult or paediatric patients.

(see SmPC for the full indication). It contains caspofungin as the active substance and it is administered by slow intravenous infusion.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of CASPOFUNGIN Stada, together with measures to minimise such risks and the proposed studies for learning more about CASPOFUNGIN Stada's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of CASPOFUNGIN Stada is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of CASPOFUNGIN Stada are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of CASPOFUNGIN Stada. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	• Increase in liver enzymes • Hypersensitivity reactions including histamine-mediated allergic reactions and SJS / TEN • Drug resistance • Drug-drug interaction: rifampicin and other inducers of drug clearance • Drug-drug interaction: cyclosporin A • Drug-drug interaction: tacrolimus
Important potential risks	• None
Missing information	• Exposure during pregnancy • Additional data on safety and effectiveness in neonates and infants < 3 months of age

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of CASPOFUNGIN Stada.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for CASPOFUNGIN Stada.