PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion (caspofungin).

This is a summary of the risk management plan (RMP) for Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion. The RMP details important risks of caspofungin's, how these risks can be minimised, and how more information will be obtained about caspofungin risks and uncertainties (missing information).

Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion is authorised for

- 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, neutropenic adult or paediatric patients.

It contains caspofungin as the active substance and it is given by intravenous route.

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

Important risks of Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion, together with measures to minimise such 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. 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 Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion. 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/use in special patient populations etc.).

Table 7 Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	• Liver toxicity, increased values of some liver tests (Hepatotoxicity /increase in liver enzymes) • Allergic reactions, rash, facial swelling, angioedema, pruritus, sensation of warmth, or bronchospasm (Hypersensitivity (including anaphylaxis and histamine-mediated allergic reactions)) • Resistance of the fungi to the medicine (Drug resistance) • Interaction between caspofungin and drugs that initiates or enhances the expression of an enzyme (Drug interaction with rifampicin and other inducers of drug clearance) • Interaction between caspofungin and cyclosporine A (Drug interaction with cyclosporine A) • Interaction between caspofungin and tacrolimus (Drug interaction with tacrolimus)
Important potential risks	• None
Missing information	• Exposure during pregnancy • Additional data on the 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 Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion.

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

There are no studies required for Caspofungin Mylan 50 mg powder for concentrate for solution for infusion / Caspofungin Mylan 70 mg powder for concentrate for solution for infusion / Mymicyas 50 mg powder for concentrate for solution for infusion / Mymicyas 70 mg powder for concentrate for solution for infusion.