Part VI: Summary of the risk management plan

Summary of risk management plan for Micafungin Bioglan 50 mg and 100 mg powder for concentrate for solution for infusion (Micafungin)

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

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

I. The medicine and what is used for

Micafungin Bioglan is authorized for the treatment of invasive candidiasis, treatment of oesophageal candidiasis and prophylaxis of Candida infection (see SmPC for the full indication). It contains micafungin as the active substance, and it is administered intravenously.

II. Risks associated with the medicine and activities to minimize or further characterize the risks.

Important risks of Micafungin Bioglan, together with measures to minimise such risks and the proposed studies for learning more about Micafungin Bioglan, 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 of the product addressed to patients and healthcare professionals respectively;
- 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.

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

II.A List of important risks and missing information

Important risks of Micafungin Bioglan 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 Micafungin Bioglan. 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	- Haemolytic adverse events including disseminated intravascular coagulation (DIC)
Important potential risks	- Development of resistant strains
Missing information	- None

II.B Summary of important risks

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

II.C Post-authorization 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 Micafungin Bioglan.

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

There are no studies required for Micafungin Bioglan.