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

This is a summary of the risk management plan (RMP) for Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion. The RMP details important risks of Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion's risks and uncertainties (missing information).

Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion's RMP.

I. The medicine and what it is used for

Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion is authorised

Adults, adolescents ≥ 16 years of age and elderly:

- Treatment of invasive candidiasis,
- Treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate
- Prophylaxis of *Candida* infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count <500 cells/µl) for 10 or more days.

Children (including neonates) and adolescents < 16 years of age:

- Treatment of invasive candidiasis
- Prophylaxis of *Candida* infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count <500 cells/µl) for 10 or more days.

(see SmPC for the full indication). It contains micafungin as the active substance, and it is given as an intravenous infusion.

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

Important risks of Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion'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.

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 Hikma 50 mg | 100 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. 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 Hikma 50 mg | 100 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);

Summary of safety concerns	
Important identified risks	- Haemolytic AEs including disseminated intravascular coagulation
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-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 Micafungin Hikma 50 mg | 100 mg powder for concentrate for solution for infusion.

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

For the reference product Mycamine a surveillance study (category 3) of resistant strain development for the important potential risk "Development of resistant strains" is ongoing.