PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Anidulafungin Fresenius Kabi 100 mg powder for concentrate for solution for infusion

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

Anidulafungin Fresenius Kabi 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 it should be used.

I. The medicine and what it is used for

Anidulafungin Fresenius Kabi 100 mg powder for concentrate for solution for infusion contains anidulafungin, a medicine given intravenously (through or within a vein) in adult patients to treat a type of fungal infection of the blood or other internal organs called invasive candidiasis. The infection is caused by fungal cells (yeasts) called *Candida*. Anidulafungin belongs to a group of medicines called echinocandins. These medicines are used to treat serious fungal infections. Anidulafungin prevents normal development of fungal cell walls. In the presence of anidulafungin, fungal cells have incomplete or defective cell walls, making them fragile or unable to grow.

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

Important risks of Anidulafungin Fresenius Kabi 100 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 the medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package insert addressed to 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, 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 Anidulafungin Fresenius Kabi 100 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 Anidulafungin Fresenius Kabi 100 mg powder for concentrate for solution for infusion are risks that need special management activities to further investigate or minimise the risk, so that the medicinal product can be taken safely. 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 Anidulafungin Fresenius Kabi 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.

List of important risks and missing information	
Important identified risks	• Anaphylaxis and infusion-associated reactions • Hepatobiliary events
Important potential risks	• Convulsions • Anaesthetic exacerbation of infusion-associated reactions • QT Prolongation/torsade de pointes
Missing information	• Use in children/adolescents • Use in elderly • Use in pregnant women • Resistance

II.B Summary of important risks

The safety information in the proposed Anidulafungin Fresenius Kabi 100 mg powder for concentrate for solution for infusion Product Information is aligned with the reference medicinal product.

II.C Post-authorisation development plan

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

Not applicable.

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

Not applicable.