Part VI: Summary of the risk management plan

Summary of risk management plan for Anidulafungin Reig Jofre 100 mg powder for concentrate for solution for infusion (Anidulafungin)

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

Anidulafungin Reig Jofre 100 mg powder for concentrate for solution for infusion summary of product characteristics (SmPC)[2] and its package leaflet give essential information to healthcare professionals and patients on how Anidulafungin Reig Jofre 100 mg powder for concentrate for solution for infusion should be used.

I. The medicine and what it is used for

Anidulafungin Reig Jofre 100 mg powder for concentrate for solution for infusion is authorised for treatment of invasive candidiasis in adult patients (see SmPC)[2] for the full indication). It contains anidulafungin 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 Anidulafungin Reig Jofre 100 mg powder for concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Anidulafungin Reig Jofre 's risks, are outlined below.

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

- Specific information: 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, including Periodic Safety Update Report 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 Reig Jofre 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 Reig Jofre 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 Anidulafungin Reig Jofre 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);

List of important risks and missing information	
Important identified risks	• Anaphylaxis and infusion-associated reactions • Hepatobiliary events • Convulsions
Important potential risks	• Exacerbation of infusion associated reactions by anaesthetics • QT Prolongation/Torsade de Pointes
Missing information	• Use in children and adolescents • Use in elderly population • Use in pregnant women • Resistance

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 conditions of the marketing authorisation or specific obligation of Anidulafungin Reig are Jofre 100 mg powder for concentrate for solution for infusion.

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

There are no studies required for Anidulafungin Reig Jofre 100 mg powder for concentrate for solution for infusion.