Part VI: Summary of the risk management plan

Summary of risk management plan for Ambidap 350 mg/500 mg powder for solution for injection/infusion (daptomycin)

This is a summary of the risk management plan (RMP) for Ambidap 350 mg/500 mg powder for solution for injection/infusion. Throughout this summary product name to refer as Ambidap. The RMP details important risks of Ambidap, how these risks can be minimised, and how more information will be obtained about Ambidap's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Ambidap's RMP.

II. The medicine and what it is used for

Ambidap is indicated for the treatment of the following infections.

- Adult and paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections (cSSTI).
- Adult patients with right-sided infective endocarditis (RIE) due to *Staphylococcus aureus*. It is recommended that the decision to use daptomycin should take into account the antibacterial susceptibility of the organism and should be based on expert advice.
- Adult and paediatric (1 to 17 years of age) patients with *Staphylococcus aureus* bacteraemia (SAB). In adults, use in bacteraemia should be associated with RIE or with cSSTI, while in paediatric patients, use in bacteraemia should be associated with cSSTI.

Daptomycin is active against Gram positive bacteria only. In mixed infections where Gram negative and/or certain types of anaerobic bacteria are suspected, Daptomycin should be co-administered with appropriate antibacterial agent(s).

It contains daptomycin as the active substance and it is administered by intravenous route.

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

Important risks of Ambidap together with measures to minimise such risks and the proposed studies for learning more about Ambidap'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 the case of Ambidap, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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 Ambidap are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Ambidap. 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).

Important identified risks	• None
Important potential risks	• None
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 Ambidap.

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

There are no studies required for Ambidap.