Part VI: Summary of the risk management plan

Summary of risk management plan for Daptomycin 350 mg and 500 mg powder for solution for injection or infusion and Daptomycin RR 350 mg/500 mg powder for solution for injection or infusion (Daptomycin)

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

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

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

I. The medicine and what it is used for

Daptomycin is indicated for the treatment of the following infections:

- Adults 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 coadministered with appropriate antibacterial agent(s).

It contains daptomycin as the active substance and it is given by intravenous injection or infusion.

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

Important risks of Daptomycin, together with measures to minimise such risks and the proposed studies for learning more about Daptomycin'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, including PSUR assessment (if applicable) and signal management activity, 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 Daptomycin 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 Daptomycin. 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 Daptomycin.

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

There are no studies required for Daptomycin.