EU Risk Management Plan for Daptomycin Powder for solution for injection/infusion

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Daptomycin 350 and 500 mg powder for solution for injection/infusion.

This is a summary of the risk management plan (RMP) for Daptomycin 350 and 500 mg powder for solution for injection/infusion. The RMP details important risks of Daptomycin and how more information will be obtained about the risks and uncertainties (missing information) of Daptomycin 350 and 500 mg powder for solution for injection/infusion.

Daptomycin 350 and 500 mg powder for solution for injection/infusion's SmPC and its package leaflet give essential information to healthcare professionals and patients on how the proposed product 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 350 mg and 500 mg Powder for solution for injection/infusion are authorised 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 take into account the antibacterial susceptibility of the organism and 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.

Both Daptomycin 350 and 500 mg powder for solution for injection/infusion contain daptomycin as active substance and are administered intravenously (inside the vein).

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

Important risks of Daptomycin 350 and 500 mg powder for solution for injection/infusion, together with measures to minimise such risks about Daptomycin 350 and 500 mg powder for solution for injection/infusion, 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 (only with 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 Daptomycin 350 and 500 mg powder for solution for injection/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 Daptomycin 350 and 500 mg powder for solution for injection/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	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the Summary of Product Characteristics is aligned to the reference medicinal product.

EU Risk Management Plan for Daptomycin Powder for solution for injection/infusion

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.