Part VI: Summary of the risk management plan

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

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

The summary of product characteristics (SmPC) for *Daptomycin hameln* 350 *mg and 500 mg powder for solution for injection/infusion* and the associated package leaflets give essential information to healthcare professionals and patients on how these products should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP for *Daptomycin hameln* 350 *mg and 500 mg powder for solution for injection/infusion*.

I. The medicine and what it is used for

Daptomycin is authorized for the treatment of complicated skin and soft tissue infections (cSSTI) in adults and paediatric patients, *Staphylococcus aureus* bacteraemia (SAB) when associated with cSSTI in adults and paediatric patients (1 to 17 years of age) and right-sided infective endocarditis (RIE) due to *S. aureus* in adults (see SmPC for the full indication). It contains daptomycin as the active substance and it is given by intravenous infusion or injection (in adults only).

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

Important risks of, *Daptomycin hameln* 350 *mg and 500 mg powder for solution for injection/infusion* together with measures to minimise such risks and the proposed studies for learning more about the risks associated with treatment with *Daptomycin hameln* 350 *mg 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 (e.g. with or without a 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 hameln* 350 *mg 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 hameln* 350 *mg 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 (e.g. on the long-term use of the medicine).

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

As the active substance of this product (daptomycin has been used for decades) and its safety concerns are well-known there were no safety concerns applicable for this EU RMP based on the requirement to present only the important identified or potential risks and missing information linked to further pharmacovigilance activities or additional risk minimization measures in the EU.

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 a specific obligation for *Daptomycin hameln* 350 *mg and 500 mg powder for solution for injection/infusion.*

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

There are no studies required for *Daptomycin hameln* 350 *mg and 500 mg powder for solution for injection/infusion*.