Part VI: Summary of the risk management plan

Summary of risk management plan for *Vancomycin hameln*

This is a summary of the risk management plan (RMP) for *Vancomycin hameln*. The RMP details important risks of *Vancomycin hameln*, 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 *Vancomycin hameln* 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 *Vancomycin hameln*.

I. The medicine and what it is used for

Vancomycin hameln is authorised for the treatment of the following serious bacterial infections:

- infections of the skin and tissues below the skin,
- bone and joint infections,
- infection of the lungs called "pneumonia",
- infection of the inside lining of the heart (endocarditis) and
- to prevent endocarditis in patients at risk when undergoing major surgical procedures.

Vancomycin hameln can be given orally in adults and children for the treatment of infection of the mucosa of the small and the large intestines with damage to the mucosae (pseudomembranous colitis), caused by the *Clostridioides difficile* bacterium. It contains vancomycin hydrochloride as the active substance, and it is given either as an intravenous infusion or as an oral solution.

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

Important risks of *Vancomycin hameln,* together with measures to minimise such risks and the proposed studies for learning more about the risks associated with treatment with *Vancomycin hameln*, 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 *Vancomycin hameln* 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 *Vancomycin hameln*. 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

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 *Vancomycin hameln*.

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

There are no studies required for *Vancomycin hameln*.