Part VI: Summary of the risk management plan

Summary of risk management plan for Vancomycin

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

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

I. The medicine and what it is used for

Vancomycin is authorised for:

- complicated skin and bloodstream infections (cSSTI)
- bone and joint infections
- community-acquired pneumonia (CAP)
- nosocomial pneumonia (HAP), including ventilator-associated pneumonia (VAP) endocarditis.

Vancomycin is the active substance that is administered intravenously. The doses of Vancomycin should be individualized for each patient according to the body weight and the age group.

Reig Jofre's vancomycin-containing-products are presented in the following pharmaceutical form:

- Powder for concentrate for solution for infusion.

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

Important risks of Vancomycin, together with measures to minimise such risks and the proposed studies for learning more about Vancomycin 's risks, are outlined below.

Measures to minimise the risks identified for these medicinal products can be:

- Specific information: 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, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Vancomycin together with measures to minimise the risk are not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Vancomycin, together with measures to minimize 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, together with measures to minimisation.

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);

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 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 imposed as a condition of the marketing authorisation Vancomycin.

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

Post-authorization development plan has not been deemed necessary for Vancomycin.