PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Vancomycin Mylan 500 mg and 1000 mg (vancomycin)

This is a summary of the risk management plan (RMP) for Vancomycin Mylan 500 mg and 1000 mg. The RMP details important risks of vancomycin, how these risks can be minimised, and how more information will be obtained about vancomycin's risks and uncertainties (missing information).

Vancomycin Mylan 500 mg and 1000 mg's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of Vancomycin Mylan 500 mg and 1000 mg's RMP.

I. The medicine and what it is used for

Vancomycin Mylan 500 mg and 1000 mg is authorised for the treatment of the following infections:

- complicated skin and soft tissue infections (cSSTI)
- bone and joint infections
- community acquired pneumonia (CAP)
- hospital acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)
- infective endocarditis
- bacteraemia that occurs in association with, or is suspected to be associated with, any of the above.

Vancomycin is also indicated in all age groups for the perioperative antibacterial prophylaxis in patients that are at high risk of developing bacterial endocarditis when undergoing major surgical procedures.

Oral administration

Vancomycin is indicated in all age groups for the treatment of Clostridium difficile infection (CDI)

Consideration should be given to official guidance on the appropriate use of antibacterial agents. It contains vancomycin as the active substance and it is given as infusion by intravenous route or via oral route of administration.

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

Important risks of Vancomycin Mylan 500 mg and 1000 mg, together with measures to minimise such risks and the proposed studies for learning more about Vancomycin Mylan 500 mg and 1000 mg'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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, 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 Mylan 500 mg and 1000 mg are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. 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 Mylan 500 mg and 1000 mg. 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/use in special patient populations etc.)

Table 4 Part VI: Summary of safety concerns

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 which are conditions of the marketing authorisation or specific obligation of Vancomycin Mylan 500 mg and 1000 mg.

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

There are no studies required for Vancomycin Mylan 500 mg and 1000 mg.