Part VI: Summary of the risk management plan

Summary of risk management plan for Vancomcyin Orion (vancomycin)

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

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

Important new concerns or changes to the current ones will be included in updates of the RMP.

I. The medicine and what it is used for

Vancomycin Orion is authorised for treatment of the following serious infections:

- infections of the skin and tissues below the skin
- infection of the inside lining of the heart (endocarditis) and to prevent endocarditis in patients at risk when undergoing major surgical procedures
- infections of bones and joints
- infection in central nervous system.
- infection of the lungs called "pneumonia"
- infection in the blood linked to the infections listed above.

It contains vancomycin as the active substance and it is given as intravenous infusion.

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

Important risks of Vancomycin Orion, 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 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 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 vancomcyin is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Vancomycin Orion 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. 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	Toxic effects on ears (Ototoxicity)
	Toxic effects on kidneys (Nephrotoxicity)
	Heart stops beating (Cardiac arrest)
	Severe acute hypersensitivity reaction (Anaphylaxis)
	Overgrowth of microbes (e.g. bacteria or fungi) that are not sensitive to vancomycin (Overgrowth of non-susceptible organisms)
	Bowel inflammation (colitis) associated with antibiotic therapy (Antibiotic associated colitis)
	Severe skin reactions
Important potential risks	Use in children (Pediatric patients)
	Toxic effects on blood cells (Hematotoxicity)
Missing information	Administration during pregnancy (Pregnancy)

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

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 Orion.

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

There are no studies required for Vancomycin Orion.