PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Ertapenem:

Ertapenem is a Carbapenem derivative which inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). In Escherichia coli, affinity is strongest to PBPs 2 and 3.

This is a summary of the risk management plan (RMP) for Ertapenem. The RMP details important risks of Ertapenem, how these risks can be minimised, and how more

information will be obtained about Ertapenem's risks and uncertainties (missing information).

Ertapenem's summary of product characteristics (SmPC) gives essential information to healthcare professionals and patients on how Ertapenem should be used. Important new concerns or changes to the current ones will be included in updates of Ertapenem's RMP.

I. The medicine and what it's used for:

Treatment

Ertapenem 1 g powder for concentrate for solution for infusion is indicated in paediatric patients (3 months to 17 years of age) and in adults for the treatment of the following infections when caused by bacteria known or very likely to be susceptible to ertapenem and when parenteral therapy is required:

- Intra-abdominal infections
- Community acquired pneumonia
- Acute gynaecological infections
- Diabetic foot infections of the skin and soft tissue

Prevention

Ertapenem 1 g powder for concentrate for solution for infusion is indicated in adults for the prophylaxis of surgical site infection following elective colorectal surgery.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

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

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the summary of product characteristics (SmPC) addressed to patients and healthcare professionals.

- Important advice on the medicine's packaging.
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without Prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

II.A. List of important risks and missing information

Important risks of Ertapenem are risks that need special risk management activities to further investigate or minimize 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 enough proof of a link with the use of Ertapenem. 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).

Table 2: Summary of safety concerns

Important Identified Risks	• Hypersensitivity/anaphylactic reactions • Drug interactions with valproic acid or divalproex sodium • Drug interaction with probenecid • Pseudomembranous colitis • Seizure
Important Potential Risks	• Drug resistance
Missing Information	• Use in pregnancy • Use in patient < 3 months of age

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 Ertapenem.

II.C.2 Other Studies in Post Authorisation Development Plan

There are no studies required for Ertapenem.