Part VI: Summary of the risk management plan

Summary of risk management plan for Meropenem Enexi 500 mg/1 g powder for solution for injection/infusion

This is a summary of the risk management plan (RMP) for Meropenem Enexi 500 mg/1 g powder for solution for injection/infusion. The RMP details important risks of Meropenem Enexi 500 mg/1 g powder for solution for injection/infusion how these risks can be minimised, and how more information will be obtained about Meropenem Enexi powder for solution for injection/infusion's risks and uncertainties (missing information).

Meropenem Enexi 500 mg/1 g powder for solution for injection/infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Meropenem Enexi should be used.

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

Enexi 500 mg/1 g powder for solution for injection/infusion's RMP.

I. The medicine and what it is used for

Meropenem Enexi 500 mg/1 g powder for solution for injection/infusion is authorised for :

- Severe pneumonia, including hospital and ventilator-associated pneumonia.
- Broncho-pulmonary infections in cystic fibrosis
- Complicated urinary tract infections
- Complicated intra-abdominal infections
- Intra- and post-partum infections
- Complicated skin and soft tissue infections
- Acute bacterial meningitis

(see SmPC for the full indication). It contains meropenem as the active substance and it is given by intravenous injection or intravenous infusion.

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

Important risks of Meropenem Enexi, together with measures to minimise such risks and the proposed studies for learning more about Meropenem Enexi'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 so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use Meropenem Enexi is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of Meropenem Enexi 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 Meropenem Enexi. 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).

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 Meropenem Enexi 500 mg/1 g powder for solution for injection/infusion.

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

There are no studies required for Meropenem Enexi 500 mg/1 g powder for solution for injection/infusion.

Part VII: Annexes

Annex 1 – EudraVigilance Interface

Not Applicable

Annex 2 - Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable

Annex 4 - Specific adverse drug reaction follow-up forms

Not Applicable

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not Applicable

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not Applicable

Annex 7 - Other supporting data (including referenced material)

Not applicable

Annex 8 - Summary of changes to the risk management plan over time

Not applicable