PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Meropenem Navamedic (Meropenem Trihydrate)

This is a summary of the risk management plan (RMP) for Meropenem Navamedic. No important or potential risks or missing information have been identified for Meropenem.

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

I. The medicine and what it is used for

Meropenem Navamedic is authorised for the treatment of the following infections in adults and children aged 3 months and older:

- 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

Meropenem may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection

Meropenem may be used in the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

(see SmPC for the full indication).

It contains Meropenem Trihydrate as the active substance and it is given by intravenous injection or infusion.

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

Important risks of Meropenem Navamedic, together with measures to minimise such risks and the proposed studies for learning more about Meropenem Navamedic '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.

II.A List of important risks and missing information

Important risks 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 this medicine.
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).

No important or potential risks or missing information have been identified for Meropenem Navamedic.

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 Navamedic.

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

There are no studies required for Meropenem Navamedic.