Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for 'Meropenem B. Braun 500 mg and 1000 mg, Powder and Solvent for Solution for Infusion' (Meropenem)

This is a summary of the risk management plan (RMP) for 'Meropenem B. Braun 500 mg and 1000 mg, Powder and Solvent for Solution for Infusion' (hereafter referred as Meropenem B. Braun). The RMP details important risks of 'Meropenem B. Braun', how these risks can be minimised, and how more information will be obtained about 'Meropenem B. Braun's' risks and uncertainties (missing information).

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

I. The Medicine and What it is Used for

'Meropenem B. Braun' is authorised to treat adults and children aged 3 months and older for:

- Infection affecting the lungs (pneumonia)
- Lung and bronchial infections in patients suffering from cystic fibrosis
- Complicated urinary tract infections
- Complicated infections in the abdomen
- Infections that you can catch during or after the delivery
- Complicated skin and soft tissues infections
- Acute bacterial infection of the brain (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 to treat bacterial infection of the blood which might be associated with a type of infection mentioned above.

It contains meropenem as the active substance and it is given intravenously (i.v.).

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of 'Meropenem B. Braun', together with measures to minimise such risks and the proposed studies for learning more about 'Meropenem B. Braun'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 PL 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 are regularly analysed, 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 'Meropenem B. Braun' 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 B. Braun'. 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 yet been established 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.

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 'Meropenem B. Braun'.

II.C.2 Other Studies in Post-authorisation Development Plan

There are no studies required for 'Meropenem B. Braun'.