Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (1)

Meropenem ASH 500 mg prášek pro injekční/infuzní roztok

Meropenem ASH 1000 mg prášek pro injekční/infuzní roztok

Administrativní informace:

Léčivá látka/látky	meropenem
Léková forma/formy	prášek pro injekční/infuzní roztok
Síla/síly	500 mg, 1000 mg
Držitel rozhodnutí o registraci	ASH, s.r.o.
Registrační číslo/čísla	15/006/23-C, 15/007/23-C
Verze a datum plánu řízení rizik	verze 1.0, 18.06.2024

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

1) Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů

Summary of risk management plan for Meropenem ASH 500 mg powder for solution for injection/infusion / Meropenem ASH 1000 mg powder for solution for injection/infusion (Meropenem)

This is a summary of the risk management plan (RMP) for Meropenem ASH 500 mg powder for solution for injection/infusion / Meropenem ASH 1000 mg powder for solution for injection/infusion. The RMP details important risks of Meropenem ASH 500 mg powder for solution for injection/infusion / Meropenem ASH 1000 mg powder for solution for injection/infusion how these risks can be minimised and how more information will be obtained about Meropenem ASH 500 mg powder for solution for injection/infusion / Meropenem ASH 1000 mg powder for solution for injection/infusion 's risks and uncertainties (missing information).

Meropenem ASH 500 mg powder for solution for injection/infusion / Meropenem ASH 1000 mg 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 ASH 500 mg powder for solution for injection/infusion / Meropenem ASH 1000 mg powder for solution for injection/infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Meropenem ASH 500 mg powder for solution for injection/infusion / Meropenem ASH 1000 mg powder for solution for injection/infusion 's RMP.

I. The medicine and what it is used for

Meropenem ASH 500 mg/ Meropenem ASH 1000 mg 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 ASH 500 mg / Meropenem ASH 1000 mg may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

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

Meropenem ASH 500 mg/ Meropenem ASH 1000 mg contains meropenem trihydrate as active substance in form of powder for solution for injection or infusion and it is given by the intravenous route of administration.

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

Important risks of Meropenem ASH 500 mg/ Meropenem ASH 1000 mg, together with measures to minimise such risks and the proposed studies for learning more Meropenem ASH 500 mg/ Meropenem ASH 1000 mg '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***.

II.A List of important risks and missing information

Important risks of Meropenem ASH 500 mg/ Meropenem ASH 1000 mg 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 ASH 500 mg/ Meropenem ASH 1000 mg. 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	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 ASH 500 mg/ Meropenem ASH 1000 mg.

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

There are no studies required for Meropenem ASH 500 mg/ Meropenem ASH 1000 mg.