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)

Ertapenem ASH 1 g prášek pro koncentrát pro infuzní roztok

Administrativní informace:

Léčivá látka/látky	ertapenem
Léková forma/formy	prášek pro koncentrát pro infuzní roztok
Síla/síly	1 g
Držitel rozhodnutí o registraci	ASH, s.r.o.
Registrační číslo/čísla	15/118/22-C
Verze a datum plánu řízení rizik	verze 1.0, 03.02.2025

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 Ertapenem ASH (ertapenem)

This is a summary of the risk management plan (RMP) for Ertapenem ASH. The RMP details important risks of Ertapenem ASH how these risks can be minimised and how more information will be obtained about Ertapenem ASH's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Ertapenem ASH's RMP.

I. The medicine and what it is used for

Ertapenem ASH is authorised for paediatric patients (aged 3 months to 17 years) and adults for the treatment of the following infections when they are caused by bacteria susceptible or very likely to be susceptible to ertapenem and when parenteral treatment is required:

1. Intra-abdominal infections
2. Community-acquired pneumonia
3. Acute gynaecological infections,
4. Skin and soft tissue infections in the diabetic foot

Ertapenem ASH is indicated in adults for the prophylaxis of surgical site infection following elective colorectal surgery (see SmPC for the full indication).

Ertapenem ASH contains ertapenem sodium as the active substance 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 Ertapenem ASH, together with measures to minimise such risks and the proposed studies for learning more about Ertapenem ASH'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 Ertapenem ASH 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 Ertapenem ASH. 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 Ertapenem ASH.

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

There are no studies required for Ertapenem ASH.