Part VI: Summary of the risk management plan

Summary of risk management plan for Andatin

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

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

I. The medicine and what it is used for

Andatin is authorised for

- complicated intra-abdominal infections
- severe pneumonia including hospital and ventilator-associated pneumonia
- intra- and post-partum infections
- complicated urinary tract-infections
- complicated skin and soft-tissue infections

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.

It contains 500 mg imipenem and 500 mg cilastatin as the active substances and it is given by infusion.

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

Important risks of Andatin, together with measures to minimise such risks and the proposed studies for learning more about Andatin'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, including PSUR assessment 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 Andatin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or taken. 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 Andatin. 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 longterm use of the medicine).

Summary of safety concerns	
Important identified risk	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 Andatin.

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

There are no studies required for Andatin, powder for solution for infusion.