Part VI: Summary of the risk management plan

Summary of risk management plan for Amikacin Afortas (amikacin), solution for injection

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

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

I. The medicine and what it is used for

Amikacin Afortas is primarily indicated for:

Serious infections starting from lung, urinary tract or bowel. Intra-abdominal infections. Endocarditis. Initial treatment of infections in neutropenic patients. Treatment in adults, children, neonates and premature infants.

It contains amikacin as the active substance and it is given by intramuscular or intravenous use.

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

Important risks of Amikacin Afortas, together with measures to minimise such risks and the proposed studies for learning more about Amikacin Afortas risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- 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 Amikacin Afortas are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 Amikacin Afortas. 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).

Summary of safety concerns	
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 Amikacin Afortas.

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

There are no studies required for Amikacin Afortas.