RMP version 5.1

Part VI: Summary of risk management plan

Moxifloxacin Fresenius Kabi 400 mg/250 ml solution for infusion

This is a summary of the RMP for Moxifloxacin Fresenius Kabi. The RMP details important risks of Moxifloxacin Fresenius Kabi and how these risks can be minimised.

Moxifloxacin Fresenius Kabi SmPC and its PL give essential information to healthcare professionals and patients on how Moxifloxacin Fresenius Kabi should be used.

Important new safety concerns or changes to the current ones will be included in updates of the Moxifloxacin Fresenius Kabi RMP.

I. The medicine and what it is used for

Moxifloxacin Fresenius Kabi is indicated for the treatment of:

- Community acquired pneumonia (CAP)
- Complicated skin and skin structure infections (cSSSI)

Moxifloxacin should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.

It contains moxifloxacin hydrochloride as active substance and it is administered by intravenous route. If medically indicated the solution for infusion can be administered via a T-tube, together with compatible infusion solutions.

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

Important risks of Moxifloxacin Fresenius Kabi, together with measures to minimise such risks and the proposed studies for learning more about Moxifloxacin Fresenius Kabi 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 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 Moxifloxacin Fresenius Kabi 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 Moxifloxacin Fresenius Kabi. 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

Not Applicable

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 Moxifloxacin Fresenius Kabi.

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

There are no on-going or closed studies for Moxifloxacin Fresenius Kabi.