Summary of risk management plan for Moloxin (moxifloxacin) solution for infusion

This is a summary of the risk management plan (RMP) for Moloxin solution for infusion. The RMP details important risks of Moloxin solution for infusion and how more information will be obtained about moxifloxacin 's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Moloxin solution for infusion is authorised for the treatment of community acquired pneumonia and complicated skin and skin structure infections (see SmPC for the full indication). It contains moxifloxacin as the active substance and it is given by intravenous administration.

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

Important risks of Moloxin solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Moloxin'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 the case of Moloxin solution for infusion, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment and follow up questionnaires so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of moxifloxacin is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Moloxin solution for infusion 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. 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	Long-lasting and/or potentially irreversible serious adverse reactions
	Aortic aneurysm and aortic dissection
	Heart valve regurgitation/incompetence
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Long-lasting and/or potentially irreversible serious adverse reactions	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.4, 4.8.* Additional risk minimisation measures: *Direct Healthcare Professional Communications.*

Important identified risk: Aortic aneurysm and aortic dissection	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.4, 4.8.* Additional risk minimisation measures: *Direct Healthcare Professional Communications*

Important identified risk: Heart valve regurgitation/incompetence	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.4, 4.8.* Additional risk minimisation measures: *Direct Healthcare Professional Communications*

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 Moloxin solution for infusion.

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

There are no studies required for Moloxin solution for infusion.