Part VI: Summary of the risk management plan

Summary of risk management plan for Moloxin (moxifloxacin) film-coated tablets

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

Moloxin film-coated tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Moloxin 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 film-coated tablets are authorised for the treatment of bacterial infections in patients of 18 years and older caused by bacteria susceptible to moxifloxacin. In acute bacterial sinusitis and acute exacerbations of chronic obstructive pulmonary disease including bronchitis moxifloxacin should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections or when these have failed:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute exacerbations of chronic obstructive pulmonary disease including bronchitis (adequately diagnosed)
- Community acquired pneumonia, except severe cases
- Mild to moderate pelvic inflammatory disease (i.e. infections of female upper genital tract, including salpingitis and endometritis), without an associated tubo-ovarian or pelvic abscess.

Moloxin film-coated tablets are not recommended for use in monotherapy of mild to moderate pelvic inflammatory disease but should be given in combination with another appropriate antibacterial agent (e.g. a cephalosporin) due to increasing moxifloxacin resistance of Neisseria gonorrhoeae unless moxifloxacin-resistant Neisseria gonorrhoeae can be excluded.

Moloxin film-coated tablets may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous moxifloxacin for the following indications:

- Community-acquired pneumonia

- Complicated skin and skin structure infections

Moloxin film-coated tablets should not be used to initiate therapy for any type of skin and skin structure infection or in severe community-acquired pneumonia.

(see SmPC for the full indication). Moloxin film-coated tablets contain moxifloxacin as the active substance and it are given by oral administration.

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

Important risks of Moloxin film-coated tablets, 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 film-coated tablets, 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*.

II.A List of important risks and missing information

Important risks of Moloxin film-coated tablets 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 Moloxin film-coated tablets. 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);

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List of important risks and missing information	
Important identified risks	Prolonged, potentially irreversible, serious suspected adverse drug reactions that last 30 days or more
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Prolonged, potentially irreversible, serious suspected adverse drug reactions that last 30 days or more	
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 film-coated tablets.

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

There are no studies required for Moloxin film-coated tablets.

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	Prolonged, potentially irreversible, serious suspected adverse drug reactions that last 30 days or more
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Prolonged, potentially irreversible, serious suspected adverse drug reactions that last 30 days or more	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.4, 4.8.* Additional risk minimisation measures: *Direct Healthcare Professional Communications.*

1.8.2	Moxifloxacin
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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.