Part VI: Summary of the risk management plan

Summary of risk management plan for [MOXIFLOXACIN]

This is a summary of the risk management plan (RMP) for [MOXIFLOXACIN] 400 mg film-coated tablets. The RMP details important risks of [MOXIFLOXACIN] 400 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about [MOXIFLOXACIN] 400 mg film-coated tablets risks and uncertainties (missing information).
[MOXIFLOXACIN] 400 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [MOXIFLOXACIN] 400 mg film-coated tablets should be used.

This summary of the RMP for [MOXIFLOXACIN] 400 mg film-coated tablets should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).
Important new concerns or changes to the current ones will be included in updates of [MOXIFLOXACIN]'s RMP.

I. The medicine and what it is used for

Moxifloxacin Accord contains the active substance moxifloxacin, which belongs to a group of antibiotics called fluoroquinolones. Moxifloxacin Accord works by killing bacteria that cause infections.
Moxifloxacin Accord is used in patients aged 18 years and above for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Moxifloxacin Accord should only be used to treat these infections when usual antibiotics cannot be used or have not worked:

- Infection of the sinuses, sudden worsening of long term inflammation of the airways or infection of the lungs (pneumonia) acquired outside the hospital (except severe cases).
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and infections of the uterus mucous membrane.

Moxifloxacin Accord is not sufficient on their own for treating this kind of infection. Therefore, another antibiotic in addition to Moxifloxacin Accord should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see section 2 of the patient leaflet. What you need to know before you take Moxifloxacin Accord, Warnings and precautions, Talk to your doctor before taking Moxifloxacin Accord).

If the following bacterial infections have shown improvement during initial treatment with moxifloxacin solution for infusion, Moxifloxacin Accord may also be prescribed by your doctor to complete the course of therapy:
Infection of the lungs (pneumonia) acquired outside the hospital, infections of the skin and soft tissue.
Moxifloxacin Accord should not be used to initiate therapy for any type of infections of the skin and soft tissue or in severe infections of the lungs.

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

Important risks of [MOXIFLOXACIN] 400 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about [MOXIFLOXACIN] 400 mg film-coated tablets 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 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] 400 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of [MOXIFLOXACIN] 400 mg 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 [MOXIFLOXACIN] 400 mg 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);

Summary of safety concerns	
Important identified risks	• Aortic aneurysm and dissection • Prolonged, disabling and potentially irreversible serious adverse drug reactions (musculoskeletal, nervous, psychiatric and senses)
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Important Identified Risk: Aortic aneurysm and dissection	
Risk minimisation measures	*Routine risk minimization measure:* Section 4.4 of SmPC *Additional risk minimization measures:* Educational materials for physicians

Important Identified Risk: Prolonged, disabling and potentially irreversible serious adverse drug reactions (musculoskeletal, nervous, psychiatric and senses)	
Risk minimisation measures	*Routine risk minimization measure:* Sections 4.3, 4.4, 4.8 of SmPC *Additional risk minimization measures:* Educational materials for physicians

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] 400 mg film-coated tablets.

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

There are no studies required for [MOXIFLOXACIN] 400 mg film-coated tablets.