Part VI: Summary of the risk management plan

Summary of risk management plan for Levofloxacin Macure

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

I. The medicine and what it is used for

Levofloxacin Macure is authorised for the treatment of adults with

- Acute pyelonephritis and complicated urinary tract infections.
- Chronic bacterial prostatitis.
- Inhalation Anthrax: post-exposure prophylaxis and curative treatment

Levofloxacin Macure is only indicated for the treatment of the following infections when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections

- Acute bacterial sinusitis.
- Acute exacerbation of chronic obstructive pulmonary disease including bronchitis.
- Community-acquired pneumonia.
- Complicated skin and soft tissue infections.
- Uncomplicated cystitis.

Levofloxacin Macure can also be used to complete course of therapy in patients initially treated with intravenous levofloxacin.

It contains 500 mg as the active substance, and it is given orally.

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

Important risks of Levofloxacin Macure, together with measures to minimise such risks and the proposed studies for learning more about Levofloxacin Macure'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 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 Levofloxacin Macure are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Levofloxacin Macure. 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.

Summary of safety concerns	
Important identified risk	Disabling and potentially long-lasting side effects
	Aortic aneurysm and dissection
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Disabling and potentially long-lasting side effects	
Risk minimisation measures	Routine risk minimization measures **SmPC** Section 4.4, Special warnings and precautions for use

Important identified risk: Disabling and potentially long-lasting side effects	
	Section 4.8, Undesirable effects **PIL** Section 2, What you need to know before you take levofloxacin Section 4, Possible side effects Pack size: Limited pack size Additional risk minimisation measures Direct Healthcare Professional Communication
Additional pharmacovigilance activities	None

Important identified risk: Aortic aneurysm and dissection	
Risk minimisation measures	Routine risk minimization measures **SmPC** Section 4.4, Special warnings and precautions for use Section 4.8, Undesirable effects **PIL** Section 2, What you need to know before you take levofloxacin Section 4, Possible side effects Pack size: Limited pack size Additional risk minimisation measures Direct Healthcare Professional Communication
Additional pharmacovigilance activities	None

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 Levofloxacin Macure.

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

There are no studies required for Levofloxacin Macure.