Part VI: Summary of the risk management plan

VI.1 Summary of risk management plan for Xiflodrop (moxifloxacin)

This is a summary of the risk management plan (RMP) for Xiflodrop. The RMP details important risks of Xiflodrop, how these risks can be minimised, and how more information will be obtained about <invented name>'s risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Xiflodrop is authorised for topical treatment of purulent bacterial conjunctivitis, caused by moxifloxacin susceptible strains (see SmPC for the full indication). It contains moxifloxacin as the active substance and it is given topically.

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

Important risks of Xiflodrop, together with measures to minimise such risks and the proposed studies for learning more about Xiflodrop'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.

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

II.A List of important risks and missing information

Important risks of Xiflodrop are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely <administered> <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 <invented name>. 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	Corneal disorders
	Hypersensitivity
	Off-label (intraocular use)
Important potential risks	Musculoskeletal and connective tissue disorder
	QT-interval prolongation
	Emergence of resistance
Missing information	Use in treatment of conjunctivitis in neonates
	Use in treatment of *Chlamydia trachomatis* infection in infants and toddlers under 2 years

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 Xiflodrop.

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

There are no studies required for Xiflodrop.