Part VI: Summary of the risk management plan

Summary of risk management plan for [Product Name] (5 mg/ml chloramphenicol and 1 mg/ml dexamethasone), eyedrops

This is a summary of the risk management plan (RMP) for [Product Name] (5 mg/ml chloramphenicol and 1 mg/ml dexamethasone) eyedrops. The RMP details important risks of [Product name], how these risks can be minimised, and how more information will be obtained about [Product name]'s risks and uncertainties (missing information).

[Product name] summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Product name] should be used.

I. The medicine and what it is used for

Treatment of anterior segment ocular inflammation in cases where treatment with corticosteroids is indicated and there is a concurrent or a high risk of bacterial infection caused by chloramphenicol susceptible bacteria.
Consideration should be given to official local guidance on the appropriate use of antibacterial agents.

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

Important risks of [Product Name], together with measures to minimise such risks and the proposed studies for learning more about [Product Name]'s risks, are outlined below.

Measures to minimize the risks identified for medicinal products are:

- 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* 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 [Product Name] are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 [Product Name], 1 mg/ml and 5 mg/ml, eye drops. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Risk Minimisation measures
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 [Product Name]

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

There are no studies required for [Product Name]