Part VI: Summary of the risk management plan

Summary of risk management plan Xorox Eye Ointment

This is a summary of the risk management plan (RMP) for Xorox Eye Ointment. The RMP details important risks of Xorox Eye Ointment, how these risks can be minimised, and how more information will be obtained about Xorox Eye Ointment risks and uncertainties.

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

I. The medicine and what it is used for

Xorox Eye ointment is a White to whitish grey, homogeneous eye ointment contains Aciclovir as an active ingredient and it is given by Ocular/ Ophthalmic route as Eye ointment of 3% strength.

1 g Xorox Eye ointment contains 30 mg aciclovir. One single dose (1 cm of ointment) contains 1.2 mg aciclovir. In addition, it contains white Vaseline as single excipient.

Xorox Eye ointment is available on prescription only. The indications claimed for eye ointment is local treatment for superficial, acute and recurrent herpes simplex infections of cornea in adult patients.

Aciclovir is a purine nucleoside analogue and shows in vitro high activity against herpes simplex virus type 1 and 2, as well as against the Varicella-Zoster virus. Aciclovir is a first-line-option for treatment of prophylaxis of herpes simplex and varicella zoster virus infections.

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

Important risks of Xorox Eye Ointment, together with measures to minimise such risks for learning more about Xorox Eye Ointment 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 including PSUR assessment 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 Xorox Eye Ointment 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 Xorox Eye Ointment. 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.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

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

Not Applicable.