Summary of risk management plan for Olopatadine 1 mg/ml Eye drops, Solution

This is a summary of the risk management plan (RMP) for Olopatadine 1 mg/ml Eye drops, Solution. The RMP details important risks of Olopatadine 1 mg/ml Eye drops, Solution, how these risks can be minimised and how more information will be obtained about Olopatadine 1 mg/ml Eye drops, Solution in risks and uncertainties (missing information).

Olopatadine's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Olopatadine 1 mg/ml Eye drops, Solution should be used.

I. The medicine and what it is used for

Olopatadine 1 mg/ml Eye drops, Solution are indicated for treatment of ocular signs and symptoms of seasonal allergic conjunctivitis.

It contains Olopatadine as active substances and it is given by ocular route.

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

Important risks of Olopatadine 1 mg/ml Eye drops, Solution, together with measures to minimise such risks and the proposed studies for learning more about Olopatadine'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, including PSUR assessment as applicable 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 Olopatadine 1 mg/ml Eye drops, Solution 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 Olopatadine 1 mg/ml Eye drops, Solution. 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 longterm use of the medicine).

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 sufficient to manage the risks of the 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 Olopatadine 1 mg/ml Eye drops, Solution.

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

There are no studies required for Olopatadine 1 mg/ml Eye drops, Solution.