

Part VI: Summary of the risk management plan

Summary of risk management plan for Olopatadine Hydrochloride eye drops solution (1mg/ml) (olopatadine hydrochloride)

This is a summary of the risk management plan (RMP) for olopatadine hydrochloride eye drops solution (1mg/ml). The RMP details important risks of olopatadine hydrochloride eye drops solution (1mg/ml), how these risks can be minimised, and how more information will be obtained about olopatadine hydrochloride eye drops solution (1mg/ml)'s risks and uncertainties (missing information).

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

This summary of the RMP for olopatadine hydrochloride eye drops solution (1mg/ml) should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of olopatadine hydrochloride eye drops solution (1mg/ml)'s RMP.

I. The medicine and what it is used for

Olopatadine hydrochloride eye drops solution (1mg/ml) is indicated for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis..

Further information about the evaluation of olopatadine hydrochloride eye drops solution (1mg/ml)'s benefits can be found in olopatadine Hydrochloride eye drops solution (1mg/ml)'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage. [Pre-authorisation RMP: link to the EPAR summary landing page \(http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con619189.pdf\)](http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con619189.pdf).

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

Important risks of olopatadine hydrochloride eye drops solution (1mg/ml), together with measures to minimise such risks and the proposed studies for learning more about olopatadine hydrochloride eye drops solution (1mg/ml)'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 and signal management activity, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of olopatadine Hydrochloride eye drops solution (1mg/ml) is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of olopatadine hydrochloride eye drops solution (1mg/ml) 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 olopatadine hydrochloride eye drops solution (1mg/ml). 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);

List of important risk and missing information	
Important identified risks	<ul style="list-style-type: none"> • Hypersensitivity to the active ingredient or excipients

Important potential risks	<ul style="list-style-type: none">• Keratopathy (for the excipient benzalkonium chloride)
Missing information	<ul style="list-style-type: none">• Exposure during pregnancy• Exposure through human milk• Exposure in children < 3 years old

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 olopatadine hydrochloride eye drops solution (1mg/ml).

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

There are no studies required for olopatadine hydrochloride eye drops solution (1mg/ml).