Summary of risk management plan for

Ocutifex 0.25 mg/ml eye drops, solution in single-dose container

(ketotifen hydrogen fumarate)

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This is a summary of the risk management plan (RMP) for Ocutifex 0.25 mg/ml eye drops, solution in single-dose container. The RMP details important risks of Ocutifex 0.25 mg/ml eye drops, solution in single-dose container, how these risks can be minimised, and how more information will be obtained about Ocutifex 0.25 mg/ml eye drops, solution in single-dose container's risks and uncertainties (missing information).

Ocutifex 0.25 mg/ml eye drops, solution in single-dose container's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ocutifex 0.25 mg/ml eye drops, solution in single-dose container should be used.

Important new concerns or changes to the current ones will be included in updates of Ocutifex 0.25 mg/ml eye drops, solution in single-dose container's RMP.

I. The medicine and what it is used for

Ocutifex 0.25 mg/ml eye drops, solution in single-dose container is authorised for the symptomatic treatment of seasonal allergic conjunctivitis (see SmPC for the full indication). It contains ketotifen hydrogen fumarate as the active substance 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 Ocutifex 0.25 mg/ml eye drops, solution in single-dose container, together with measures to minimise such risks and the proposed studies for learning more about Ocutifex 0.25 mg/ml eye drops, solution in single-dose container'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, 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 Ocutifex 0.25 mg/ml eye drops, solution in single-dose container is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Ocutifex 0.25 mg/ml eye drops, solution in single-dose container 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 Ocutifex 0.25 mg/ml eye drops, solution in single-dose container. 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 risks and missing information	
Important identified risks	None
Important potential risks	Potential for off-label use (for other ophthalmic indications)
Missing information	Use in children younger than 3 years of age Use during pregnancy

II.B Summary of important risks

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

Important potential risk Potential for off-label use (for other ophthalmic indications)	
Evidence for linking the risk to the medicine	There has been no reported use of Ocutifex 0.25 mg/ml eye drops, solution in single-dose container in a different disease. In the countries where the product can be obtained without a prescription there is a possibility that patients with a different eye disease may treat themselves with Ocutifex 0.25 mg/ml eye drops, solution in single-dose container.
Risk factors and risk groups	Patients with ophthalmic eye disease other than seasonal allergic conjunctivitis.
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.1* *PL section 1* Additional risk minimisation measures: None

Missing information Use in children younger than 3 years of age	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.2* *PL sections 2 and 3* Additional risk minimisation measures: None

Missing information Use during pregnancy	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.6* *PL section 2* Additional risk minimisation measures: None

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 Ocutifex 0.25 mg/ml eye drops, solution in single-dose container.

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

There are no studies required for Ocutifex 0.25 mg/ml eye drops, solution in single-dose container.