

Part VI: Summary of the risk management plan

Summary of risk management plan for Ketotifene Polifarma 0,25 mg/ml collirio soluzione (ketotifen)

This is a summary of the risk management plan (RMP) for Ketotifene Polifarma 0,25 mg/ml collirio soluzione (as ketotifen). The RMP details important risks of Ketotifene Polifarma 0,25 mg/ml collirio soluzione, how these risks can be minimised, and how more information will be obtained about risks of Ketotifene Polifarma 0,25 mg/ml collirio soluzione and uncertainties (missing information).

Summary of product characteristics (SmPC) of Ketotifene Polifarma 0,25 mg/ml collirio soluzione and package leaflet give essential information to healthcare professionals and patients on how Ketotifene Polifarma 0,25 mg/ml collirio soluzione should be used.

Important new concerns or changes to the current ones will be included in updates of RMP of Ketotifene Polifarma 0,25 mg/ml collirio soluzione.

I. The medicine and what it used for

Ketotifene Polifarma 0,25 mg/ml collirio soluzione is authorised for the symptomatic treatment of seasonal allergic conjunctivitis. It contains ketotifen 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 Ketotifene Polifarma 0,25 mg/ml collirio soluzione, together with measures to minimise such risks and the proposed studies for learning more about risks of Ketotifene Polifarma 0,25 mg/ml collirio soluzione, 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 Ketotifene Polifarma 0,25 mg/ml collirio soluzione is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of Ketotifene Polifarma 0,25 mg/ml collirio soluzione 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 of Ketotifene Polifarma 0,25 mg/ml collirio soluzione. 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.

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 Ketotifene Polifarma 0,25 mg/ml, collirio soluzione.

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

There are no studies required for Ketotifene Polifarma 0,25 mg/ml, collirio soluzione..