Part VI: Summary of the risk management plan

Summary of risk management plan for Ketotifen Horus Pharma 0.25mg/ml, eye drops solution ® (ketotifen hydrogen fumarate)

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

Ketotifen Horus Pharma 0.25 mg/ml, eye drops solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ketotifen Horus Pharma 0.25 mg/ml, eye drops solution should be used.

I. The medicine and what it is used for

KETOTIFEN HORUS PHARMA 0.25mg/ml, eye drops solution is used for symptomatic treatment of seasonal allergic conjunctivitis. It contains Ketotifen hydrogen fumarate as the active substance and it is given in eye drops for local route (ocular route).

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

Important risks of Ketotifen Horus Pharma 0.25 mg/ml, eye drops solution, together with measures to minimise such risks and the proposed studies for learning more about Ketotifen Horus Pharma 0.25 mg/ml, eye drops, solution risks, are outlined below.

Measures to minimise the risks identified for this medicinal product are:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- The authorised pack size — the amount of medicine in a bottle is chosen so to ensure that the medicine is used correctly;

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed 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 Ketotifen Horus Pharma 0.25 mg/ml, eye drops solution is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Ketotifen Horus Pharma 0.25 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 could 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 Ketotifen Horus Pharma 0.25 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 long-term use of the medicine).

List of important risks and missing information	
Important identified risks	**None**
Important potential risks	**None**
Missing information	- **Use in pregnancy**

II.B Summary of important risks

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

Missing information : Use during pregnancy	
Risk factors and risk groups	Pregnant female patients
Risk minimisation measures	<u>Routine risk communication :</u> - SmPC section 4.6 "Fertility, pregnancy and lactation" PIL section 2 "Pregnancy and breast-feeding".

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 Ketotifen Horus Pharma 0.25 mg/ml, eye drops solution.

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

Not applicable.