Part VI: Summary of the risk management plan

Summary of risk management plan is reported in exact layout for publication in next page

Summary of risk management plan for OPHTHAJOD 50 mg/ml eye drops, solution (Povidone, iodinated g 5 (0.5% available iodine)).

This is a summary of the risk management plan (RMP) for OPHTHAJOD 50 mg/ml eye drops, solution. The RMP details important risks of OPHTHAJOD 50 mg/ml eye drops, solution, how these risks can be minimised, and how more information will be obtained about OPHTHAJOD 50 mg/ml eye drops, solution's risks and uncertainties (missing information).

OPHTHAJOD 50 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 OPHTHAJOD 50 mg/ml eye drops, solution should be used.

Important new concerns or changes to the current ones will be included in updates of OPHTHAJOD 50 mg/ml eye drops, solution's RMP.

I. The medicine and what it is used for

OPHTHAJOD 50 mg/ml eye drops, solution is authorised for preparation of the surgical field (eyelids, lashes and cheeks) and irrigation of the ocular surface (cornea, conjunctiva and palpebral fornices). It contains povidone, iodinated g 5 (0.5% available iodine) as the active substance and it is given for ophthalmic use only. The product is contraindicated in infants up to one month of age.

It must not be administered for irrigation and intraocular or periocular injection.

The product must not be administered simultaneously with eye drops containing mercurial preservatives.

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

Important risks of OPHTHAJOD 50 mg/ml eye drops, solution, together with measures to minimise such risks and the proposed studies for learning more about OPHTHAJOD 50 mg/ml eye drops, solution '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 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 OPHTHAJOD 50 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. 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 OPHTHAJOD 50 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	• *none*

II.B Summary of important risks

The safety information in the proposed product information is aligned to medicinal product containing Povidone, iodinated g 5 (0.5% available iodine) already registered and marketed in several European Countries for more than 10 years.

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 OPHTHAJOD 50 mg/ml eye drops, solution. II.C.2 Other studies in post-authorisation development plan

There are no studies required for OPHTHAJOD 50 mg/ml eye drops, solution.