Part VI: Summary of the risk management plan

Summary of Risk Management Plan for Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml

This is a summary of the risk management plan (RMP) for Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml. The RMP details important risks of Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml, how these risks can be minimised, and how more information will be obtained about Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml risks and uncertainties (missing information).

Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml should be used.

Important new concerns or changes to the current ones will be included in updates of Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml 's RMP.

I. The Medicine and What It is used for

Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml is authorised for the reduction of elevated intra-ocular pressure in various conditions. It is indicated in adult patients with ocular hypertension; adult patients with chronic open-angle glaucoma including aphakic patients; some adult patients with secondary glaucoma. It contains timolol maleate as the active substance and it is given topically (eye drops, solution).

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

Important risks of Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml, together with measures to minimise such risks and the proposed studies for learning more about Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml 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 Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml is not yet available, is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Eyopto, øjendråber, opløsning 2,5 & 5 mg/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 Eyopto, øjendråber, opløsning 2,5 & 5 mg/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 risks and missing information	
Important identified risks	• Safety in patients with respiratory disorders • Safety in patients with cardiac disorders • Safety in patients with vascular disorders • Increased risk for anaphylactic reactions and poor response to adrenaline • Choroidal detachment after filtration procedures • Combination with CYP2D6 inhibitors (e.g. quinidine, fluoxetine, paroxetine)
Important potential risks	• Masking of hyperglycaemia / diabetes • Masking of signs of hyperthyroidism • Block of beta-adrenergic agonist effects during surgical anaesthesia e.g. of adrenalin • Corneal diseases • Concomitant administration with oral calcium channel blocker, beta-adrenergic blocking agents, antiarrhythmics (including amiodarone), digitalis glycosides, parasympathomimetics and guanethidine
Missing information	• Use in pregnancy • Long-term treatment in paediatric populations (eyedrops)

II.B Summary of Important Risks

The safety information in the 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 Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Eyopto, øjendråber, opløsning 2,5 & 5 mg/ml.