# Part VI: Summary of the risk management plan

## VI.1 Summary of risk management plan for Vizioblok® (timolol)

This is a summary of the risk management plan (RMP) for Vizioblok®. The RMP details important risks of Vizioblok®., how these risks can be minimised, and how more information will be obtained about Vizioblok®'s risks and uncertainties (missing information). Vizioblok®'s summary of product information (PI) give essential information to healthcare professionals and patients on how Vizioblok® should be used.

## I. The medicine and what it is used for

Vizioblok® is authorised for use in adults for:

- Ocular hypertension
- Patients with chronic open-angle glaucoma including aphakic patients
- Patients with secondary glaucoma.

The product contains timolol as the active substance and it is given by topical route of administration (eye drops).

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

Important risks of Vizioblok®, together with measures to minimise such risks and the proposed studies for learning more about Vizioblok®'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 PI 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.
- The medicine's label – The information or physical appearance either inside or outside the cartoon of the medicine ensures that the correct medicine is used

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report 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 timolol is not yet available, it is listed under 'missing information' below.

## *II.A List of important risks and missing information*

Important risks of Vizioblok® 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 Vizioblok®. 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<br>• Safety in patients with cardiac disorders<br>• Safety in patients with vascular disorders<br>• Increase risk for anaphylactic reactions and poor response to adrenaline<br>• Choroidal detachment after filtration procedures<br>• Combination with Cytochrome P450 2D6 (CYP2D6) inhibitors (e.g. quinidine, fluoxetine, paroxetine) |
| Important potential risks | • Masking of hypoglycaemia/diabetes<br>• Masking of signs of hyperthyroidism<br>• Block of beta-adrenergic agonist effects during surgical anaesthesia e.g. of adrenaline<br>• Corneal diseases<br>• Concomitant administration with oral calcium channel blockers, beta-adrenergic blocking agents, antiarrhythmics (including amiodarone), digitalis glycosides, parasympathomimetics, and guanethidine |
| Missing information | • Use in pregnancy<br>• Long term treatment in paediatrics population (eye drops) |

## *II.B Summary of important risks*

The safety information in the product information is aligned to the reference medicinal product (Timoptol®, MAH: Merck Sharp & Dohme Limited).

## *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 Vizioblok®.

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

There are no other studies required for Vizioblok®.