Summary of risk management plan for Dorzolamide/Timolol Pharmabide (Dorzolamide hydrochloride / Timolol maleate)

This is a summary of the risk management plan (RMP) for Dorzolamide/ Timolol Pharmabide. The RMP details important risks of Dorzolamide/ Timolol Pharmabide, and how more information will be obtained about Dorzolamide/ Timolol Pharmabide 's risks and uncertainties (missing information).

Dorzolamide/ Timolol Pharmabide 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dorzolamide/ Timolol Pharmabide should be used.

Important new concerns or changes to the current ones will be included in updates of Dorzolamide/ Timolol Pharmabide 's RMP.

I. The medicine and what it is used for

Dorzolamide/ Timolol Pharmabide is authorised for:

the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or pseudoexfoliative glaucoma when topical beta-blocker monotherapy is not sufficient. (see SmPC for the full indication).

It contains Dorzolamide and Timolol as the active substances and it is given by topical application, eye drops.

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

Important risks of Dorzolamide/ Timolol Pharmabide, together with measures to minimise such risks and the proposed studies for learning more about Dorzolamide/ Timolol Pharmabide '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, 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 Dorzolamide/ Timolol Pharmabide is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Dorzolamide/ Timolol Pharmabide 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 Dorzolamide/ Timolol Pharmabide. 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	• Systemic beta-blockade associated side effects including worsening of pre-existing cardiac and vascular disorders • Respiratory disorders (including bronchospasm, worsening of pre-existing reactive respiratory diseases) • Severe hypersensitivity reactions
Important potential risks	• Masking of hypoglycemic symptoms in patients with diabetes mellitus • Drug interaction with other oral or topical beta-blocking agents or carbonic anhydrase inhibitors, and CYP2D6 inhibitors • UrolithiasisChoroidal detachment • Corneal oedema
Missing information	• Use in pregnancy or in breast-feeding women • Use in patients with hepatic impairment or severe renal impairment • Use in children younger than 2 years of age

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 Dorzolamide/ Timolol Pharmabide.

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

There are no studies required for Dorzolamide/ Timolol Pharmabide.