Part VI: Summary of the risk management plan

Summary of Risk Management Plan for Dorzolamid/Timolol Pharmathen

This is a summary of the risk management plan (RMP) for Dorzolamid/Timolol Pharmathen. The RMP details important risks of Dorzolamid/Timolol Pharmathen, how these risks can be minimised, and how more information will be obtained about Dorzolamid/Timolol Pharmathen risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Dorzolamid/Timolol Pharmathen RMP.

I. The Medicine and What It is used for

Dorzolamid/Timolol Pharmathen is authorized for the treatment of elevated intra-ocular pressure (IOP) in patients with open-angle glaucoma or pseudo-exfoliative glaucoma when topical beta- blocker monotherapy is not sufficient. It contains dorzolamide hydrochloride and timolol maleate as the active substances 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 Dorzolamid/Timolol Pharmathen, together with measures to minimise such risks and the proposed studies for learning more about Dorzolamid/Timolol Pharmathen 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 Dorzolamid/Timolol Pharmathen is not yet available, is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Dorzolamid/Timolol Pharmathen 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 Dorzolamid/Timolol Pharmathen. 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	• Choroidal detachment • Corneal edema • 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 • Urolithiasis
Missing information	• Use in pregnancy/ breast-feeding women • Use in patients with hepatic or severe renal impairment • Use in children younger than 2 years of age

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 Dorzolamid/Timolol Pharmathen.

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

There are no studies required for Dorzolamid/Timolol Pharmathen.