Part VI: Summary of the risk management plan

Summary of risk management plan for Dorzolamid/Timolol "PharmaSwiss" (dorzolamide, timolol eye drops solution)

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

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

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

I. The medicine and what it is used for

Dorzolamid/Timolol "PharmaSwiss" 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.

It contains dorzolamide and timolol as the active substances, and it is administered locally as eye drops.

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

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

II.A List of important risks and missing information

Important risks of Dorzolamid/ Timolol "PharmaSwiss" 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 "PharmaSwiss". 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 Cardiac disorders Vascular disorders Respiratory disorders (including bronchospasm, worsening of pre-existing reactive respiratory diseases) Ophthalmic disorders (including corneal disorders and choroidal detachment) Hypoglycemia/diabetes Interaction with surgical anesthesia Anaphylactic reactions Drug interaction with other beta-blocking agents, CYP2D6 inhibitors, adrenaline
Important potential risks	Eye infection (including bacterial keratitis) or injury Sulphonamide-associated severe hypersensitivity reactions Urolithiasis Medication error
Missing information	Use in pregnancy/ breast-feeding women Use in patients with hepatic or severe renal impairment Use in paediatric population

**List of safety concerns adopted from the reference product Cosopt (Merck Sharp&Dohme B.V)*

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 Dorzolamid/ Timolol "PharmaSwiss".

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

There are no studies required for Dorzolamid/ Timolol "PharmaSwiss".