Part VI: Summary of the risk management plan

Summary of risk management plan for Dorzolamid Pharmaswiss (dorzolamide, eye drops solution)

This is a summary of the risk management plan (RMP) for Dorzolamid Pharmaswiss. The RMP details important risks of Dorzolamid Pharmaswiss and how more information will be obtained about Dorzolamid Pharmaswiss risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Dorzolamid Pharmaswiss 's RMP.

I. The medicine and what it is used for

Dorzolamid Pharmaswiss is authorised as adjunctive therapy to beta-blockers, as monotherapy in patients unresponsive to beta-blockers or in whom beta- blockers are contraindicated, in the treatment of elevated intra-ocular pressure in: ocular hypertension, open-angle glaucoma and pseudoexfoliative glaucoma (see SmPC for the full indication). It contains dorzolamide as active substance, 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 Pharmaswiss, together with measures to minimise such risks and the proposed studies for learning more about Dorzolamid Pharmaswiss, 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.

II.A List of important risks and missing information

Important risks of Dorzolamid 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 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	None
Important potential risks	None
Missing information	None

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 Pharmaswiss.

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

There are no studies required for Dorzolamid Pharmaswiss.