13 Part VI: Summary of the risk management plan (RMP) - Dorzolamide hydrochloride, 20 mg/ml, Eye drops, Solution

This is a summary of the RMP for dorzolamide hydrochloride, 20 mg/ml, eye drops, solution. The RMP details important risks of dorzolamide hydrochloride, eye drops solution, how these risks can be minimized, and how more information will be obtained about dorzolamide hydrochloride's risks and uncertainties (missing information).

Dorzolamide hydrochloride, eye drops solution's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how dorzolamide hydrochloride eye drops solution should be used.

Important new concerns or changes to the current ones will be included in updates of the dorzolamide hydrochloride eye drops solution's RMP.

13.1 Part VI: I. The medicine and what it is used for

Dorzolamide hydrochloride, eye drops solution is indicated to lower raised pressure in the eye and to treat glaucoma (high fluid pressure inside the eye which may damage the optic nerve that carries information from the eye to the brain). This medicine can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers).

It contains dorzolamide hydrochloride as active substance and is given is given through ophthalmic route in the form of eye drops, solution (20 mg/ml).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of dorzolamide hydrochloride, eye drops solution, together with measures to minimize such risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Reports (PSURs) assessment (if applicable) 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 hydrochloride, eye drops solution is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of dorzolamide hydrochloride, eye drops solution are risks that need special risk management activities to further investigate or minimize 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 dorzolamide hydrochloride, eye drops solution. 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).

Table 13-1 List of important risks and missing information

Important identified risks	Use in patients with corneal decompensation
Important potential risks	The risk of metabolic acidosis
	Effects of carbonic anhydrase inhibition
	Long term use of preserved eye drops
Missing information	Hepatic impairment
	Use in pregnant and breastfeeding women
	Renal impairment

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of dorzolamide hydrochloride, eye drops solution.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for dorzolamide hydrochloride, eye drops solution.

14 Part VII: Annexes

Annex 1 – EudraVigilance Interface

Available in electronic format only.