13 Part VI: Summary of the risk management plan (RMP) - Dorzolamide hydrochloride/Timolol maleate, 20 mg/ml + 5 mg/ml Eye drops, solution

This is a summary of the RMP for dorzolamide hydrochloride/timolol maleate 20 mg/ml + 5 mg/ml eye drops, solution. The RMP details important risks of dorzolamide hydrochloride/timolol maleate eye drops, solution, how these risks can be minimized, and how more information will be obtained about dorzolamide hydrochloride/timolol maleate eye drops, solution's risks and uncertainties (missing information).

Dorzolamide hydrochloride/Timolol maleate 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/timolol maleate eye drops, solution should be used.

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

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

Dorzolamide hydrochloride/timolol maleate eye drops, solution is a combination of dorzolamide hydrochloride, an ophthalmic carbonic anhydrase inhibiting active substance and timolol maleate, an ophthalmic beta-blocking active substance, both of which lower raised pressure in the eye in different ways.

Dorzolamide hydrochloride/timolol maleate eye drops, solution is prescribed to lower raised pressure within the eye in the treatment of glaucoma when beta-blocker eye drops used alone are not adequate

It contains dorzolamide hydrochloride and timolol maleate as the active substance and is given through ophthalmic route in the form of eye drops, solution (20 mg/ml + 5 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/timolol maleate 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 report (PSUR) 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/timolol maleate 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 dorzolamide hydrochloride/timolol maleate 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 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 hydrochloride/timolol maleate 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	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 or in breast-feeding women
	Use in patients with hepatic impairment or severe renal impairment
	Use in children younger than 2 years of age

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/timolol maleate 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/timolol maleate eye drops, solution.