

V.2 Additional Risk Minimisation Measures

Not applicable.

V.3 Summary table of risk minimisation measures

Not applicable.

Part VI: Summary of the risk management plan

Summary of risk management plan for Dorzolamide/Timolol 20 mg/ml + 5 mg/ml eye drops, solution.

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

Dorzolamide/timolol's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how dorzolamide/timolol 20 mg/ml + 5 mg/ml eye drops, solution should be used.

I. The medicine and what it is used for

Dorzolamide/Timolol 20 mg/ml + 5 mg/ml eye drops, solution is authorized 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 hydrochloride and Timolol maleate as active substances and it is given by ocular route.

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

Important risks of dorzolamide/timolol 20mg/ml+ 5mg/ml eye drops, solution together with measures to minimise such risks and the proposed studies for learning more about dorzolamide/timolol's risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the package insert 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 as applicable so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of dorzolamide/timolol 20mg/ml+ 5mg/ml eye drops, solution are risks that need special risk management activities to further investigate or minimise 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/timolol 20mg/ml+ 5mg/ml 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).

| 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 sufficient to manage the risks of the 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 dorzolamide/timolol 20mg/ml+ 5mg/ml eye drops, solution.

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

There are no studies required for dorzolamide/timolol 20mg/ml+ 5mg/ml eye drops, solution.