Part VI: Summary of the risk management plan

Summary of risk management plan for DUOKOPT / DUALKOPT, eye drops solution (Timolol, Dorzolamide)

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

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

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

I. The medicine and what it is used for

DUOKOPT is a preservative-free eye drop, solution which contains two active substances: dorzolamide and timolol.

- Dorzolamide belongs to a group of medicines called "carbonic anhydrase inhibitors".
- Timolol belongs to a group of medicines called "beta blockers".

It is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eyedrop medicine used alone (e.g. timolol only) is not adequate.

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

Important risks of DUOKOPT, together with measures to minimise such risks and the proposed studies for learning more about DUOKOPT's 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;
- The authorised pack size — the amount of medicine in a pack (i.e. number of single-dose containers in the box or volume of solution in the multi-dose containers is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the fact that DUOKOPT requires a prescription to be 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, 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 DUOKOPT 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 DUOKOPT. 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 identified
Important potential risks	None identified
Missing information	None identified

II.B Summary of important risks

Not applicable as no risks considered important for inclusion in the list of safety concerns.

Therefore DUOKOPT does not have additional risk minimisation activities and no additional pharmacovigilance activities are requested.

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 DUOKOPT.

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

There are no studies required for DUOKOPT.