Summary of the risk management plan for DuoTrav (travoprost/timolol)

This is a summary of the Risk Management Plan (RMP) for DuoTrav. The RMP details important risks of DuoTrav, how these risks can be minimised, and how more information will be obtained about DuoTrav's risks and uncertainties (missing information).

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

This summary of the RMP for DuoTrav should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

DuoTrav is authorised for the decrease of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. It contains travoprost 40 µg/mL and timolol 5 mg/mL (as timolol maleate) as the active substances, and it is given as eye drops.

Further information about the evaluation of DuoTrav's benefits can be found in DuoTrav's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/duotrav.

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

Important risks of DuoTrav, together with measures to minimise such risks and the proposed studies for learning more about DuoTrav'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;
- 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 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 DuoTrav 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 DuoTrav. 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 1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B: Summary of important risks

Not applicable, since there are no important risks/safety concerns.

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 DuoTrav.

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

There are no studies required for DuoTrav.