Part VI: Summary of the risk management plan

Summary of risk management plan for TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution

This is a summary of the risk management plan (RMP) for TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution. The RMP details any important risks of TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution, how these risks can be minimised, and how more information will be obtained about TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution's risks and uncertainties (missing information).

TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution should be used.

Important new concerns or changes to the current ones will be included in updates of TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution's RMP.

I. The medicine and what it is used for

TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution is authorised for the decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. It contains 40 micrograms of travoprost and 5 mg of timolol, as active substances, and it is an eye drop for ophthalmic use.

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

Any important risks of Z TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution, together with measures to minimise such risks are outlined below.

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

- Specific information, such as contraindications, 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 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 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 TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks 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 the medicinal product. 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)

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

No important risks that would need special risk management activities have been identified for TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution.

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 TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution.

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

There are no studies required for TRAVABLOC 40 mcg/ml + 5 mg/ml eye drops solution.