Part VI: Summary of the risk management plan

Summary of risk management plan for [Travoprost] 40µg/mL, eye drops, solution.
This is a summary of the risk management plan (RMP) for [Travoprost] 40µg/mL, eye drops, solution, how these risks can be minimised, and how more information will be obtained about [Travoprost] 40µg/mL, eye drops, solution risks and uncertainties (missing information).
[Travoprost] 40µg/mL, eye drops, solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Travoprost] 40µg/mL, eye drops, solution should be used.

I. The medicine and what it is used for

[Travoprost] eye drops are used to treat high pressure in the eye in adults, adolescents and children from 2 months old onward. This pressure can lead to an illness called glaucoma.

High pressure in the eye. Your eyeballs contain a clear, watery liquid which feeds the inside of the eye. Liquid is always emptying out of the eye, and more liquid is always being produced. If the eye fills up faster than it empties, the pressure inside the eye builds up. If it gets too high, it can damage your sight.

[Travoprost] is one of a group of medicines for glaucoma called prostaglandin analogues. It works by increasing the outflow of liquid, which lowers the pressure in the eye. It may be used on its own or with other drops e.g. beta-blockers, which also reduce pressure.
This medicine does not contain a preservative.

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

Important risks of [Travoprost] 40µg/mL, eye drops, solution, together with measures to minimise such risks and the proposed studies for learning more about [Travoprost] 40µg/mL, eye drops, solution 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 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 [Travoprost] 40µg/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 of [Travoprost] 40µg/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 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 [Travoprost] 40µg/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);

Summary of safety concerns	
Important identified risks	• Macular oedema • Hyperpigmentation • Hypertrichoses • Iris and uveal inflammation • Cardiac and vascular disorders • Respiratory disorders • Hypersensitivity reactions
Important potential risks	• Corneal damage and hypersensitivity due to long term use of preserved eye drops • Melanomas • Use during pregnancy and lactation
Missing information	• Potential interactions • Long term safety in the paediatric population.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference 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 [Travoprost] 40µg/mL eye drops, solution.

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

There are no studies required for [Travoprost] 40µg/mL, eye drops, solution.