Summary of risk management plan for **Travoprost Uni-Pharma 40 micrograms/ml eye drops, solution in single-dose container**

This is a summary of the risk management plan (RMP) for **Travoprost Uni-Pharma.**

The RMP details important risks of **Travoprost Uni-Pharma**, how these risks can be minimised, and how more information will be obtained about **Travoprost Uni-Pharma**'s risks and uncertainties (missing information).

Travoprost Uni-Pharma's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how **Travoprost UniPharma** should be used.

Important new concerns or changes to the current ones will be included in updates of **Travoprost Uni-Pharma**'s RMP.

I. The medicine and what it is used for

Travoprost Uni-Pharma is authorised for:

- Decrease of elevated intraocular pressure in adult patients with ocular hypertension or open-angle glaucoma.
- Decrease of elevated intraocular pressure in paediatric patients aged 2 months to < 18 years with ocular hypertension or paediatric glaucoma.

It contains 'travoprost' as the active substance and it is given by ocular administration.

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

Important risks of **Travoprost Uni-Pharma**, together with measures to minimise such risks and the proposed studies for learning more about **Travoprost Uni-Pharma** 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 **Travoprost Uni-Pharma** PSUR assessment, 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 Uni-Pharma** is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of **Travoprost Uni-Pharma** 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 **Travoprost Uni-Pharma**. 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);

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the 'reference' medicinal product.

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

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 Uni-Pharma**.

II.C.2 Other studies in post-authorisation development plan There are no

studies required for **Travoprost Uni-Pharma**.