

Summary of risk management plan for Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container.

This is a summary of the risk management plan (RMP) for **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container**.

The RMP details important risks of **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**, how these risks can be minimised, and how more information will be obtained about **Travoprost+Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**' risks and uncertainties (missing information).

**Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops** should be used.

Important new concerns or changes to the current ones will be included in updates of **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**'s RMP.

## **I. The medicine and what it is used for**

**Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops** is indicated in adults for the decrease of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta blockers or prostaglandin analogues.

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

Important risks of **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**, together with measures to minimise such risks and the proposed studies for learning more about **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**' 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/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops** 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/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops** is not yet available, it is listed under ‘missing information’ below.

### ***II.A List of important risks and missing information***

Important risks of **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops** 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/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**. 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);

<b>Summary of safety concerns</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

### ***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/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**.

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

There are no studies required for **Travoprost/Timolol Uni-Pharma 40 micrograms/ml + 5 mg/ml eye drops**.