# Summary of the risk management plan for Travatan (travoprost)

This is a summary of the risk management plan (RMP) for Travatan. The RMP details important risks of Travatan, how these risks can be minimized, and how more information will be obtained about Travatan's risks and uncertainties (missing information).

Travatan's summaries of product characteristics (SmPCs) and their package leaflets give essential information to healthcare professionals and patients on how these products should be used.

This summary of the RMP for Travatan 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 respective European Public Assessment Reports (EPARs).

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

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

Travatan is authorized for:

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

Travatan contains travoprost (eye drops, solution) as the active substance at the following strengths:

- travoprost 40 µg/mL: preserved with polyquad (PQ),
- travoprost 40 µg/mL: preserved with benzalkonium chloride (BAK),
- travoprost 40 µg/mL: preserved with sofZia (Z).

Further information about the evaluation of Travatan's benefits can be found in Travatan's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage*:*

Travatan: //ema.europa.eu/en/documents/overview/travatan-epar-summary-public_en.pdf

## II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Travatan, together with measures to minimize such risks and the proposed studies for learning more about Travatan's risks, are outlined below.

Measures to minimize 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Travatan are risks that need special risk management activities to further investigate or minimize 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 Travatan. 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-authorization development plan

## II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Travatan.

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

There are no other studies required for Travatan.