EU Risk Management Plan

Active substance(s) (INN or common name):	**Travoprost**
Pharmacotherapeutic group (ATC Code):	Ophthalmologicals – antiglaucoma preparations and miotics – prostaglandin analogues (S01E E04)
Number of medicinal products to which this RMP refers:	• 1
Product(s) concerned (brand name(s)):	Travoprost 40 micrograms/ml eye drops, solution

Data lock point for this RMP	**2014-Feb-28**	Version V1.1
Date of final sign off	**2014-Feb-28**	

Part VI Summary of the risk management plan

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Increased pressure in the eye, also called ocular hypertension, is a primary risk factor for developing open-angle glaucoma, a leading cause for blindness. In 2007, an estimated 3-6 million US people had ocular hypertension, including 4 to 7% of those over the age of 40 years. Additionally, an estimated 2.5 million people in the US had glaucoma, and over 100,000 of these were legally blind as a result.
Open angle glaucoma is a disease that is characterized by nerve damage (optic neuropathy) due to increased pressure in the eye, and occurs in about 3–4% of the world population. It has been shown that early treatment of ocular hypertension can reduce the incidence of primary open-angle glaucoma by over 50% in in high-risk patients.
In general, both diseases are more common in elderly people.

VI.2.2 Summary of treatment benefits

[Travoprost] eye drops are used to treat high pressure in the eye. 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.

VI.2.3 Unknowns relating to treatment benefits

The efficacy of travoprost in patients below the age of 18 years has not been established up to now; most studies are focussed on adult or elderly patients, the main target group of intraocular hypertension and open-angle glaucoma, and results for studies in paediatric patients have not been published yet.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Swelling inside the eye leading to disturbed vision (Macular oedema)	Percentage of occurence is not known.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Increased colouring (Hyperpigmentation)	Travoprost may permanently change the colour of the iris (the coloured part of the eye). Iris colour changes have been observed in more than 10% of travoprost-treated patients.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Increased hair growth (Hypertrichoses)	Travoprost may increase the length, thickness, colour and/or number of eyelashes and may cause unusual hair growth on the eyelids. Increased or decreased growth or number of eyelashes has been observed in up to 10% of treated patients.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Inflammation of the inner eye structures (Iris and uveal inflammation)	Redness of the eye has occurred in more than 10% of treated patients, and up to 10% of patients experience inflammation inside the eye, eye pain or swelling or eye irritation.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Disorders associated with the heart and blood vessels	Increased or decreased blood pressure and irregular,	Always take this medicine as prescribed by your doctor

(Cardiac and vascular disorders)	increased or decreased heart rate have been observed in up to 1% of patients treated with travoprost.	and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
(Respiratory disorders)	Travoprost may rarely cause breathlessness or wheezing or increase the symptoms of asthma. In up to 1% of patients treated with travoprost eyedrops, asthma, shortness of breath, cough, increased allergic symptoms, throat irritation, stuffy nose or voice changes have been observed.	If you are concerned about changes in your breathing pattern when using this medicine talk to your doctor as soon as possible.

Important potential risks

Risk	**What is known** **(Including reason why it is considered a potential risk)**
Corneal damage and hypersensitivity due to long term use of preserved eye drops	If travoprost preserved eyedrops are used for a long time, they might lead to corneal damage and hypersensitivity.
Ocular and skin melanomas	Travoprost may be associated with the development of malignant ocular and skin cancers called melanoma.
Use during pregnancy and lactation	Travoprost may be absorbed through the skin and therefore should not be used by women who are pregnant or are attempting to become pregnant. If any of the product comes into contact with the skin then it should be washed off straight away. **Do not use [Travoprost] if you are pregnant.** If you think that you may be pregnant speak with your doctor right away. If you could become pregnant you must use adequate contraception whilst you use this medicine. **Do not use [Travoprost] if you are breast feeding.** This medicine may pass into your milk. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking any medicine.

Missing information

Risk	**What is known**

Interactions with other medicinal products	Travoprost may interact with other medicinal products. However, no interaction studies have been performed.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

This is the first approved RMP for this medicinal product. Future updates to approved RMPs will be described in this section.