PUBLIC 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/Timolol Stada eye drops solution is a combination of two active substances (travoprost and timolol). Travoprost is a prostaglandin analogue which works by increasing the outflow of liquid of the eye, which lowers its pressure. Timolol is a beta blocker which works by reducing the production of fluid within the eye. The two substances work together to reduce pressure within the eye.

Travoprost/Timolol Stada eye drops are used to treat high pressure in the eye in adults, including the elderly**.** This pressure can lead to an illness called glaucoma.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of travoprost/timolol in children and adolescents below the age of 18 years have not been established. No data are available.

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)	Frequency of occurrence 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 gradually change the colour of the iris (the coloured part of the eye). Iris colour changes have been observed in up to 1 in 1000 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 1% 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 up to 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 (Cardiac and vascular disorders)	Increased or decreased blood pressure and irregular, increased or decreased heart rate have been observed in up to 1% of 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.
Respiratory disorders	Respiratory reactions, especially in patients with asthma, have been reported following administration of some ophthalmic beta-blockers (a group of drugs that timolol belongs to).	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)

Ocular and skin melanomas	Travoprost may be associated with the development of malignant ocular and skin cancers called melanoma.
Corneal damage due to the long-term use of preserved eye drops	If preserved eyedrops are used for a long time, they might lead to corneal damage and hypersensitivity.
Use during pregnancy and lactation	Travoprost/Timolol Stada must not be used in women who may become pregnant unless adequate contraceptive measures are in place. Travoprost has harmful pharmacological effects on pregnancy and/or the foetus/new-born child. There are no or limited amount of data from the use of travoprost/timolol or the individual components in pregnant women. Timolol should not be used during pregnancy unless clearly necessary.

Missing information

Risk	**What is known**
Potential interactions	No specific drug interaction studies have been performed with travoprost or timolol.
Safety and efficacy in children	The safety and efficacy of travoprost/timolol in children and adolescents below the age of 18 years have not been established. No data are available.

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

Not applicable