13.2 Part VI.2 Elements for a Public Summary

13.2.1 Part VI.2.1 Overview of disease epidemiology

Glaucoma is a group of eye diseases characterized by elevated intraocular pressure (IOP) (increased fluid pressure inside the eye) which is the second leading cause of blindness in the world. It is estimated that 66.8 million persons in the world have open-angle glaucoma, it leads to irreversible blindness if not treated [Varma R, 2012]. The proportion of people affected with open-angle glaucoma is more among age group of 40 to 80 years [Tham YC, 2014]. Open-angle glaucoma is the most common among populations of European or African descent. It is 3 times higher in blacks compared to whites [Varma R, 2012]. Risk factors include family history, increasing age, increased IOP and pseudo exfoliation (age related eye disorder with accumulation of protein fibers in the eye) [Ekstrom C, 2012], high blood pressure [Zhao D, 2014], high blood sugar [Zhao D, 2015], abnormally low activity of the thyroid gland and heart and blood vessels diseases [Girkin CA, 2004].

13.2.2 Part VI.2.2 Summary of treatment benefits

Travoprost is widely used for reducing IOP in patients with abnormal buildup of pressure within the eye that could lead to blindness. Use of travoprost eye drops induces IOP reduction from 27-30% and sustained throughout the 24-hour cycle. In December 2014, travoprost 0.004% was approved by European Medicines Agency (EMA) for use in children, aged 2 months to 18 years, with abnormally increased eye pressure. Convenience of one-day dosing and minor side effects make travoprost a good choice as first-line therapy in patients with abnormally increased eye pressure that could result in loss of eyesight [Quaranta L, 2015]. Switching to a fixed dose combination with travoprost 0.004%/timolol (beta blocker used to reduce eye pressure) 0.5% for 12 weeks significantly reduced IOP in patients who had elevated IOP despite bimatoprost/timolol treatment as per an open-label non-randomized study conducted to evaluate the efficacy and safety of travoprost 0.004%/timolol 0.5% combination at 13 European sites [Schnober D, 2015]. In comparison with fixed combinations of latanoprost/timolol, treatment with travoprost/timolol was found to be more effective in significantly reducing the eye pressure in patients with ocular hypertension (increased pressure within the eyes) associated with inflammation of uvea, the middle layer of the eye [Takeuchi M, 2016].

13.2.3 Part VI.2.3 Unknowns relating to treatment benefits

The efficacy of travoprost in patients below the age of 18 years has not been established and its use is not recommended in these patients until further data become available.

In addition, interaction studies of travoprost with other medicinal products are not available.

13.2.4 Part VI.2.4 Summary of safety concerns

Table 13-1 Important identified risks

Risk	What is known	Preventability
Build-up of fluid in the macula, an area in the center of the retina which is the light-sensitive tissue at the back of the eye (Macular edema)	Inflammation of the back of the eye is one of the side effects of travoprost but frequency is unknown. Cases of macular edema have been reported post marketing with use of travoprost.	Caution is recommended when using travoprost in patients with known risk factors for cystoid macular edema (condition with multiple cyst-like areas of fluid appearing in the macula causing swelling in retina). Patients should talk to their doctor or pharmacist if they get any side effects.
Change in color of the colored part of eye (Iris hyperpigmentation)	Changes in the color of the iris (the colored part of eye, this may affect up to 23 % of the patients) is a very common side effect of travoprost. This change may be permanent.	Patients should consult a doctor or pharmacist before using travoprost. Patients should talk to their doctor or pharmacist if they get any side effects.
Excessive hair growth over and above the normal for the age, sex and race of an individual (Hypertrichosis)	Travoprost may cause unusual hair growth on eyelids. Hypertrichosis is an uncommon side effect of travoprost. Cases of abnormal hair growth have been reported post marketing with use of travoprost.	Patients should consult a doctor or pharmacist before using travoprost. Patients should talk to their doctor or pharmacist if they get any side effects.
Inflammation of the colored portion of eye and the pigmented middle layer of the eye (Iris and uveal inflammation)	Inflammation inside the eye is one of the uncommon side effect of travoprost.	In patients with known risk factors for iris and uveal inflammation, travoprost should be used with caution. Patients should talk to their doctor or pharmacist if they get any side effects.
Disorders of heart and blood vessels (Cardiac and vascular disorders)	Shortness of breath, increased or decreased blood pressure and irregular, increased, or decreased heart rate are uncommon side effects of travoprost. Cases of increased and decreased heart rate have been reported post marketing with use of travoprost.	Patients should talk to their doctor or pharmacist if they get any side effects.

Risk	What is known	Preventability
Disorders of lung that affect breathing (Respiratory disorders)	Travoprost may rarely cause breathlessness or wheezing or increase the symptoms of asthma. Shortness of breath, asthma, respiratory disorder, throat pain, cough, difficulty in talking, nasal stuffiness and throat irritation are uncommon side effects of travoprost.	If patients are concerned about changes in their breathing pattern when using travoprost doctor should be informed as soon as possible. Patients should talk to their doctor or pharmacist if they get any side effects.
Allergic reactions (Hypersensitivity reactions)	Eye allergy and increased allergic symptoms in body are uncommon side effects of travoprost.	Patient should not take travoprost if they are allergic to travoprost or any of the other ingredients of this medicine. Patients should talk to their doctor or pharmacist if they get any side effects.

Table 13-2 Important potential risks

Risk	What is known
Damage to the transparent layer forming the front of the eye due to the use of eye drops containing chemicals (Corneal damage due to use of preserved eye drops)	Inflammation or infection of the conjunctiva (thin transparent membrane that covers the exposed white part of the eyeball (sclera) and lines the inner surface of the eyelids) or cornea and corneal disorder are uncommon side effects of travoprost.
Type of skin cancer (Melanoma)	Currently no adequate data are available about the association of melanoma and the use of travoprost.
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. Patients should not use travoprost if they are pregnant. If a patient thinks that she might be pregnant doctor should be consulted immediately. If patient could become pregnant she must use adequate contraception whilst using travoprost. Patient should not use travoprost if they are breast-feeding as it may get into milk.

Table 13-3 Missing information

Risk	What is known
Use in children (Use in pediatric population)	Travoprost is not to be used by people under 18 years of age.

Risk	What is known
	This medicine contains boric acid: which may cause toxic reactions in infants and children below 3 years of age. This medicine should be kept out of the sight and reach of children.
Potential interactions	No studies on interactions of travoprost have been performed.

13.2.5 Part VI.2.5 Summary of additional risk minimization measures by safety concern

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

This medicine has the no additional risk minimization measures.

13.2.6 Part VI.2.6 Planned post authorization development plan

None

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

N/A