7.2 Part VI.2 Elements for a Public Summary

7.2.1 Part VI.2.1 Overview of disease epidemiology

Glaucoma, an ocular eye disorder, is characterized by nerve damage in the eye as a result of high pressure within the eye. It is not a single entity and is sometimes referred to in the plural as the glaucomas. All forms of glaucoma are potentially progressive and can lead to blindness (Casson RJ, Chidlow G, Wood J, et al. 2012). Glaucoma is the second most common cause of world blindness. The estimated number of people with vision loss from glaucoma range from 5.2 to 6.7 million. This is approximately 10% of the total number of affected persons (Lee AJ, McCluskey P, 2008). These numbers are set to increase to 80 million and 11.2 million by 2020. The highest occurrence of Open-angle glaucoma occurs most commonly in Africans, and the highest occurrence of whereas angle closure glaucoma occurs most commonly in the Inuit (Cook C, Foster P, 2012). The most common forms of glaucoma are age-related but it may also be caused by e.g. long-term use of corticosteroids, high blood pressure, diabetes and smoking.

7.2.2 Part VI.2.2 Summary of treatment benefits

If detected early enough, glaucoma progression can be slowed with drug and/or surgical treatment. If left untreated, blindness may result. The most important risk factor to be treated in order to delay the development of glaucoma is high pressure in the eye. This can be achieved with drug treatment which may be monotherapy (single drug) or combination

therapy (two or more drugs). Brimonidine tartrate 2 mg/ml eye drops solution may be used alone or in combination with other medicines to reduce intra-ocular pressure. In two 1 year studies, brimonidine lowered IOP by mean values of approximately 4-6 mmHg. Clinical trials show that brimonidine is effective in combination with topical beta-blockers. Shorter term studies also suggest that brimonidine has a clinically relevant additive effect in combination with travoprost (6 weeks) and latanoprost (3 months).

7.2.3 Part VI.2.3 Unknowns relating to treatment benefits

The safety and effectiveness of brimonidine in children and adolescents (2 to 17 years of age) have not been established and therefore, its use is not recommended in children or adolescents but not contraindicated. There are no adequate data for the use of the brimonidine in pregnant women. It is not known if brimonidine is excreted in human milk. Brimonidine has not been studied in patients with hepatic or renal impairment.

7.2.4 Part VI.2.4 Summary of safety concerns

Table 7-5 Important identified risks

Risk	What is known	Preventability
Use in newborns and children younger than 2 years (Use in neonates and infants (less than 2 years of age))	In cases where brimonidine has been used as part of the medical treatment of congenital (existing at birth) glaucoma, symptoms of brimonidine overdose such as loss of consciousness, drowsiness, low blood pressure or cessation of breathing have been reported in neonates and infants (less than 2 years of age) receiving brimonidine.	Brimonidine must not be used in children younger than 2 years.
Low blood pressure (Hypotension)	Hypotension can occur rarely in 1 of 1000 to 1 of 10000 patients	Patients should tell their doctor, if they feel dizzy
Drug interactions	Antidepressive drugs, alcohol, sedative drugs, blood pressure drugs etc are known to interact.	Patients should tell their doctor about all drugs they take. The physician should discuss the interactions with the patient.
Drowsiness or sleepiness in children 2-7 years old (Somnolence in children 2-7 years of age)	In average 1-10 % of patients experience this adverse drug reaction. In children, the frequency and severity of the drowsiness or sleepiness are elevated.	Children of 2 years of age and above, especially those in the 2-7 age range and/or weighing ≤ 20 kg, should be treated with caution and closely monitored due to the high incidence and severity of drowsiness or sleepiness.
Unregular heart beat (Cardiac arrhythmia)	Palpitations/arrythmiasis (including bradycardia and tachycardia) have been reported.	Caution should be exercised in treating patients with severe or unstable and uncontrolled cardiovascular disease.
Eye allergies (lid and mucosa of the eye) (Ocular allergic type	Some patients have experienced ocular allergic type reactions (allergic conjunctivitis and allergic	The preservative in brimonidine may cause eye irritation. If allergic reactions are observed,

Risk	What is known	Preventability
reactions (allergic conjunctivitis, allergic blepharitis and high pressure in the eye (increased intraocular pressure (IOP)).	blepharitis) with brimonidine. Delayed ocular hypersensitivity reactions have been reported with brimonidine tartrate ophthalmic solution 0.2%, with some reported to be associated with a high pressure in the eye (an increase in IOP).	treatment with brimonidine should be discontinued.

Table 7-6 Important potential risks

None

Table 7-7 Missing information

Risk	What is known (Including reason why it is considered a potential risk)
Use in children and adolescents	The safety and effectiveness of brimonidine in children and adolescents (2 to 17 years of age) have not been established and therefore, its use is not recommended in children or adolescents.
Use in patients suffering from kidney and liver diseases. (Use in patients with renal and hepatic impairment)	Brimonidine has not been studied in patients with hepatic or renal impairment. Therefore, caution should be used in treating such patients.
Lack of knowledge on the use in pregnant women and if brimonidine pass into human breast milk (Use in pregnancy and lactation)	There are not enough data for the use of brimonidine in pregnant women. Brimonidine should not be used during pregnancy unless clearly necessary. It is not known if brimonidine passes into human milk but it passes into the milk of the lactating rat.

7.2.5 Part VI.2.5 Summary of risk minimisation 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 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.

7.2.6 Part VI.2.6 Planned post authorisation development plan

None

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

N/A