VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Eletriptan can be used to treat migraine headache with or without perceptual disturbance (aura) in adults.

Migraines are believed to be due to a mixture of environmental and genetic factors[1]. About two-thirds of cases run in families. Fluctuating hormone levels may also play a role: migraine affects slightly more boys than girls before puberty, but about two to three times more women than men[2].

Worldwide migraines affect nearly 15% or approximately one billion people[3]. In Europe, migraines affect 12-28% of people at some point in their lives with about 6-15% of adult men and 14-35% of adult women getting at least one yearly[4]. While symptoms resolve in about two thirds of the elderly, in between 3 and 10% they persist. In a World Health Organization (WHO) report of 2000, migraine is listed the 19th cause of disability in the world.

VI.2.2 Summary of treatment benefits

Several clinical trials have tested the effectiveness of eletriptan in the indication discussed above.

Migraine headache with or without aura

For the treatment of migraine headache, eletriptan was compared to dummy treatment (placebo) in ten main studies involving more than 6000 patients. The dosages of eletriptan ranged between 20 and 80mg. Headache relief occurred as early as 30 minutes following eletriptan treatment. A reduction of moderate or severe headache pain to no or mild pain two hours after dosing were 59-77% for the 80 mg dose, 54-65% for the 40 mg dose, 47-54% for the 20 mg dose, and 19-40% following placebo. Eletriptan was also effective in the treatment of associated symptoms of migraine such as vomiting, nausea, light sensitivity (photophobia) and sound sensitivity (phonophobia).

VI.2.3 Unknowns relating to treatment benefits

In the target population the efficacy of eletriptan has not been established in elderly, during pregnancy, in children and adolescents. There is no evidence to suggest that results would differ by gender or race.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Effects on the heart and blood vessels, inadequate heart blood flow, heart attack and stroke (Cardiovascular events (including vascular disease and cardiac disease))	Patients may develop chest pain and tightness, which may be intense and involve the throat. These may be symptoms caused by problems of the blood circulation of the heart. Rarely (may affect up to 1 in 1,000 people), stroke has been reported as an undesirable effect of eletriptan. There is also a risk of having a stroke in patients with a previous history. Eletriptan has been known to cause inadequate heart blood flow, heart attack and spasms in blood vessels.	Yes, do not take eletriptan if you have ever had heart problems Patients with a history of stroke should not take this medicine. Patients with heart problems should not be treated with this medicine.
A potentially life-threatening drug reaction that causes the body to have too much serotonin during combined use with certain medicines (Serotonin syndrome following concomitant therapy with serotonergic agents)	Signs and symptoms of serotonin syndrome may include restlessness, hallucinations, loss of coordination, fast heartbeat, increase body temperature, fast changes in blood pressure and overactive reflexes. Some medicines (commonly referred to as SSRIs), for depression and other mental disorders may increase the risk of developing serotonin syndrome during combined use with certain migraine medications.	Yes, by informing your doctor before treatment if you are taking medicines for depression or other mental disorders.

Allergic reactions (Hypersensitivity)	This medicine may cause an allergic reaction. Symptoms may include sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body). This is uncommon (may affect up to 1 in 100 people).	Yes, the medicine should not be used by patients who are allergic to eletriptan, or any of the other ingredients of this medicine.
Worsening of headaches due to overuse of the medicine (Medication overuse headache)	. If you repeatedly use any medicines for the treatment of migraine over several days or weeks, this can cause daily long-term headaches.	Yes, this medicine should not be used repeatedly.

Important potential risks

Risk	What is known
Inflammation of the large intestine (Ischaemic colitis)	There have been rare reports of inflammation of the large intestine during treatment with eletriptan.
Use in pregnancy	These is insufficient data available on the safety of this medicine in pregnancy.

Missing information

Risk	What is known
Use in elderly population (> 65 years of age)	The safety and effectiveness of eletriptan have not been studied in elderly patients, therefore the use in this group of patients is not recommended.
Use in children and adolescents (< 18 years of age (Use in the paediatric population < 18 years of age))	The safety and effectiveness of eletriptan in children aged 6 to 11 years and the effectiveness in adolescents aged 12 to 17 years have not been established yet.
Use during breastfeeding (Use in lactation)	These is insufficient data available on the safety of this medicine in breastfeeding women.

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (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.

No additional risk minimisation activities are required.

VI.2.6 Planned post authorisation development plan (if applicable)

There are no studies in the post authorisation development plan.

VI.2.7 Summary of changes to the risk management plan over time

N/A