VI.2 Elements for a public summary

VI.2.1 Overview of Disease Epidemiology

Allergic rhinoconjunctivitis

Seasonal allergic rhinitis is a common problem, affecting 15% of the European population and 20% of the American population. During childhood it is more frequent in boys. However, in adulthood is equal in both sexes. Although allergic rhinitis is more common during childhood, adolescence and early adult years, it may occur at any age.

Both genetic and environmental factors contribute to the development of allergic rhinitis. The most common allergen is the house dust mite, followed by cats and dogs.

People at most risk are:

- Patients with a history of atopy.
- Patients with a family history of rhinitis.
- First-born children.
- Immigrants.

This condition often improves over the years - particularly seasonal allergic rhinitis, which may spontaneously resolve in up to 20% of patients.

Urticaria

Approximately 20% of people experience urticaria at some time in their lives. Although urticaria can be experienced at any age, the most common age range for chronic urticaria is the fourth and fifth decades. It can occur in any race and is more frequently in women (60%). There are some factors that may lead to develop urticaria, such as stress, heat, cold, pressure, sunlight, some medical conditions, family or personal history of angioedema or drugs.

VI.2.2. Summary of treatment benefits

Ebastine is used for the treatment of the symptoms of seasonal and perennial allergic rhinitis, with or without allergic conjunctivitis, and for alleviation of itching and weal formation in urticaria of unclear origin (nettle rash).

Ebastine is a medicine that alleviates the symptoms of allergic reactions (antiallergic agent/antihistamine), but does not cause tiredness in the majority of patients.

VI.2.3 Unknowns relating to treatment benefits

The drug is not indicated for children < 12 years of age because of lacking information.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Not applicable.		

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Certain ECG alterations (QTc prolongation)	Ebastin should be used with caution in patients with certain ECG alterations (known prolongation of the QTc interval on the ECG), which can occur in some forms of heart disease. Concomitant administration of ebastine and certain antibiotics (e.g. erythromycin) or medicines used for the treatment of fungal infections (e.g. ketoconazole) can lead to elevated blood levels of ebastine. In comparison with administration of ketoconazole or erythromycin alone, this can lead to more marked changes in the ECG (increase in the QTc interval prolongation by approx. 10 ms).
Low potassium levels in the blood (Hypokalaemia)	Ebastin should be used with caution in patients with low potassium levels in the blood.

Risk	What is known (Including reason why it is considered a potential risk)
Patients with impaired liver function (Hepatic insufficiency)	Elevated liver parameters in the blood have been reported very rarely with the use of ebastine. Product should be used with caution in patients with severe impaired liver function and a dosage of 10 mg of ebastine should not be exceed in patients with mild to moderately impaired liver function.
Hives (H1-antihistamine-induced urticaria)	Hives have been reported very rarely with the use of ebastine.
Concomitant administration with certain antibiotics or medicines used to treat fungal infections(Drug interaction with substrates, inhibitors and inducers of CYP3A4)	Concomitant administration of ebastine and certain antibiotics (e.g. erythromycin) or medicines used for the treatment of fungal infections (e.g. ketoconazole) can lead to elevated blood levels of ebastine. In comparison with administration of ketoconazole or erythromycin alone, this can lead to more marked changes in the ECG (increase in the QTc interval prolongation by approx. 10 msec.)

Missing information

Risk	What is known
Not applicable.	

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.

VI.2.6 Planned post authorisation development plan

Not applicable.

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

Table 1: Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
001	12/10/2015	Not applicable.	-
002	25/08/2017	Part II SV updated Wording changes in Part I, Part II: SVIII, Part V and Part VI.	-