

## **Part VI - Summary of activities in the Risk Management Plan**

### **Elements for a Public Summary**

#### **1. Overview of disease epidemiology**

Azelastin-POS 1 mg/ml nasal spray is indicated for the treatment and prevention of the symptoms of seasonal allergic rhinitis.

Rhinitis is one of the most common diseases in the population. It is generally classified as allergic, either seasonal or perennial, or non-allergic of which there are several types. It is assumed that 25% of people are suffering from any allergy and 15% suffering from allergies are affected by their eyes and/or nose.

The most common symptoms of allergic rhinitis are nasal congestion, sneezing, itchy nose and runny nose. This is an allergic reaction to substances such as, for example, pollen from trees or flowers. If untreated, rhinitis may compromise quality of life by decreasing productivity at work and school, reducing participation in recreational activities, disrupting normal sleep patterns, and adversely affecting cognitive function.

#### **2. Summary of treatment benefits**

Azelastin-POS 1 mg/ml nasal spray contains the active ingredient azelastine hydrochloride, which belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of histamine that the body produces as part of an allergic reaction.

There are several therapeutic options for the treatment of allergic rhinitis. Among a broad range of medicinal products, tablets for oral application with antihistamines and nasal sprays containing corticosteroids are considered to be the first line agents.

Other agents, such as nasal sprays for the local application of antihistamines such as Azelastin-POS 1 mg/ml nasal spray can be added to treat the symptoms described above. Depending on the severity of symptoms the more application of the nasal spray may be sufficient if the symptoms are less severe.

#### **3. Unknowns relating to treatment benefits**

Azelastin-POS 1 mg/ml nasal sprays are used since 1992 in Europe. Therefore a lot of clinical experiences is available for the assessment of the benefit of these medicinal products.

However, due to a lack of controlled data on efficacy and safety in children below 6 years of age, Azelastin-POS 1 mg/ml nasal spray should not be used in this patient group.

Additionally there is only limited amount of data from the use of azelastine in pregnant women. Even though there is no evidence for a damaging effect even in doses higher than therapeutically used, Azelastin-POS 1 mg/ml nasal spray is not recommended during the first three months of pregnancy.

Due to the lack of data on safety and efficacy, use of Azelastin-POS 1 mg/ml nasal spray is not recommended in breast-feeding mothers.

#### 4. Summary of safety concerns

##### Important identified risks

Risk	What is known	Preventability
Hypersensitivity to the active substance or to any of the excipients	<i>Hypersensitivity reactions have been reported at a frequency of (&lt;1/10000)</i>	<i>Patients should be observed closely for hypersensitivity reactions especially during the beginning of treatment and in the case of a positive finding the use of Azelastin-POS 1 mg/ml nasal spray should be discontinued.</i>

##### Important potential risks

Risk	What is known	Preventability
None		

##### Missing information

Risk	What is known
Drug exposure during pregnancy and lactation	<i>There is insufficient safety data on the use of this product in pregnant and lactating women.</i>
Overdose	<i>There are no experiences on the administration of toxic doses of azelastine hydrochloride in human.</i>
Interactions	<i>No interactions became known for the topical use of azelastine hydrochloride until now.</i>
Use in children below the age 6	<i>There is insufficient safety data on the use of this product in these age group.</i>

#### 5. Summary of additional risk minimisation measures by safety concerns

No additional risk minimisation measures are required.

#### 6. Planned post authorization development plan

Not applicable.

#### 7. Summary of changes to the risk management plan over time

Not applicable.