

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Rhinolast 140 micrograms per Spray, Nasal Spray

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Azelastine Hydrochloride 0.1 % w/v.

Each spray actuation delivers 0.14 ml containing 140 micrograms azelastine hydrochloride per spray.

For a full list of excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Nasal spray, solution

A clear, colourless, aqueous solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the treatment of both seasonal allergic rhinitis (e.g. Hay fever) and perennial allergic rhinitis.

### 4.2 Posology and method of administration

Route of application is topical - nasal mucosa.

#### Adults and children aged 12 years and over

The standard dose is one application (0.14 ml) into each nostril twice daily (0.56 mg of azelastine hydrochloride per day).

For moderate to severe rhinitis (particularly in cases in which nasal blockage is a major presenting symptom), the dose may be increased to two applications into each nostril twice daily (1.12 mg of azelastine hydrochloride per day).

#### Elderly

No dose adjustment is necessary.

#### Children

For children aged from 5 to 12 years, the dose is one application (0.14 ml) into each nostril twice daily (0.56 mg of azelastine hydrochloride per day).

#### Method of Administration

##### *For separate bottle and pump*

Open the bottle by unscrewing the cap. Place the spray pump nozzle in the bottle and screw the pump into the bottle. Remove the protective cap. Before first using, squeeze down the collar several times until an even spray emerges. The Rhinolast spray is now ready to use.

##### *For attached pump and bottle*

Remove the protective cap. Before first using, squeeze down the collar several times until an even spray emerges. The Rhinolast spray is now ready to use.

### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

See 4.5, 4.6 and 4.7.

#### 4.5 Interaction with other medicinal products and other forms of interaction

No specific interactions have been studied.

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

There are no or limited amount of data from the use of azelastine in pregnant women. At high oral doses reproductive toxicity has been seen in animals (see section 5.3). Therefore, caution should be exercised when using azelastine nasal spray during pregnancy.

##### Breastfeeding

It is unknown whether azelastine/metabolites are excreted in human milk. Therefore, caution should be exercised when azelastine is administered to a nursing woman.

##### Fertility

Effects on fertility were seen in animal studies (see section 5.3).

#### 4.7 Effects on ability to drive and use machines

Azelastine has minor influence on the ability to drive and use machines.

In very rare cases fatigue, weariness, exhaustion, dizziness or weakness that may also be caused by the disease itself, may occur when using azelastine nasal spray. In these cases, the ability to drive and use machines may be impaired. Alcohol may enhance these effects.

#### 4.8 Undesirable effects

Commonly, dysgeusia, a bitter taste may be experienced after administration (often due to incorrect method of application, i.e. tilting the head too far backwards), which may, in rare cases, lead to nausea. This occurs more frequently at the higher dose level.

MedDRA system organ class	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Rare ≥ 1/10,000 to < 1/1,000	Very rare ≤ 1/10,000
Immune system disorders				Hypersensitivity, Anaphylactoid reaction*
Nervous system disorders	Dysgeusia (bitter taste)			Dizziness
Respiratory, thoracic and mediastinal disorders		Nasal discomfort (stinging, itching), Sneezing, Epistaxis		
Gastrointestinal disorders			Nausea	
Skin and subcutaneous tissue disorders				Rash, Pruritus, Urticaria
General disorders				Fatigue, Weakness

\*Reported for formulations containing benzalkonium chloride.

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance - Website: [www.hpra.ie](http://www.hpra.ie).

## 4.9 Overdose

The results of animal studies show that toxic doses can produce CNS symptoms, e.g. excitation, tremor, convulsions. Should these occur in humans, symptomatic and supportive treatment should be instigated as there is no specific antidote. Gastric lavage is recommended if the overdose is recent.

With the nasal route of administration overdosage reactions are not anticipated.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

ATC Code: Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use, Antiallergic agents, excl. corticosteroids. R01AC03.

Azelastine, a phthalazinone derivative of novel structure, is classified as a potent long acting anti-allergic compound with particularly strong H1 antagonist properties.

Data from animal studies show that where high levels of azelastine are achieved both inhibition and release of chemical mediators (e.g. leukotriene, histamine, serotonin) involved in allergic reaction occurs.

### 5.2 Pharmacokinetic properties

After repeated nasal application (0.14 mg) into each nostril twice daily, the plasma levels of azelastine were about 0.26 ng/ml. The levels of the active metabolite desmethylazelastine were detected at or below the lower limit of quantification (0.12 ng/ml).

After repeated oral administration, the mean C<sub>max</sub> steady state plasma levels were determined giving 3.9 ng/ml for azelastine and 1.86 ng/ml for desmethylazelastine after 2.2 mg b.i.d. azelastine which represents the therapeutic oral dose for the treatment of allergic rhinitis.

Following oral administration azelastine is rapidly absorbed showing an absolute bioavailability of 81%. Food has no influence on absorption. The volume of distribution is high indicating distribution predominantly to the peripheral tissues. The level of protein binding is low (80-95%, a level too low to give concern over drug displacement reactions).

Plasma elimination half lives after a single dose of azelastine are approximately 20 hours for azelastine and about 45 hours for N-desmethylazelastine (a therapeutically active metabolite). Excretion occurs mainly via the faeces. The sustained excretion of small amounts of the dose in the faeces suggests that some enterohepatic circulation may take place.

### 5.3 Preclinical safety data

Nonclinical data reveal no special hazard for humans based on conventional studies of genotoxicity and carcinogenicity.

Decreased fertility index was observed in male and female rats at oral doses greater than 3.0 mg/kg/day (17.5x the MHRD on a mg/m<sup>2</sup> basis).

Embryotoxic and teratogenic effects (foetal death, growth retardation and an increased incidence of skeletal abnormalities) were observed following oral dosing greater than 3, 3 and 0.3 mg/kg/day in rats, mice and rabbits, respectively (18x, 9x and 4x the MHRD on a mg/m<sup>2</sup> basis).

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hypromellose

Disodium Edetate  
Citric Acid  
Disodium Phosphate Dodecahydrate  
Sodium Chloride  
Purified Water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

3 years unopened.  
6 months after first opening.

## **6.4 Special precautions for storage**

Do not store below 8°C. Do not refrigerate.

## **6.5 Nature and contents of container**

Polyethylene bottle with polypropylene cap and polyethylene seal, containing 10ml or 20ml of aqueous solution.

Glass bottle (brown; hydrolytic Type III) with screw closure and polypropylene seal, containing 10ml or 20ml of aqueous solution.

Glass bottle (brown; hydrolytic Type III) with pump attached, containing 10ml or 20ml of aqueous solution.

10ml glass bottle (brown; hydrolytic Type III) with pump attached, containing 5ml of aqueous solution.

10ml polyethylene bottle with polypropylene cap and polyethylene seal, containing 5ml of aqueous solution.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Mylan IRE Healthcare Limited  
Unit 35/36  
Grange Parade  
Baldoyle Industrial Estate  
Dublin 13  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA2010/037/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15 December 1994

Date of last renewal: 15 December 2009

**10 DATE OF REVISION OF THE TEXT**

June 2025