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

There have been no specific studies in the elderly.

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

Proven allergy against azelastine hydrochloride.

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 interactions

No specific interactions have been studied.

4.6 Fertility, pregnancy and lactation

At high oral doses in animals, 500 times the proposed oral human daily dose, foetal death, growth retardation and an increased incidence of skeletal abnormalities occurred during reproduction toxicity testing. Due to the nasal route of administration and the low dose administered, minimal systemic exposure can be expected. However as with all medicines caution should be exercised with use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Common (1-10%) – 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.

Uncommon (01-1%) – A mild, transient irritation of the nasal mucosa may cause stinging, itching, sneezing and epistaxis.

Very rarely (< 0.01%) – Hypersensitivity reactions such as rash, pruritus and urticaria.

Immune system disorders	Very rare (1/10,000)	Hypersensitivity Anaphylactoid reaction*
Nervous system disorders	Common (>1/100 < 1/10)	Bitter taste
	Very rare (1/10,000)	Dizziness
Respiratory thoracic and mediastinal disorders	Uncommon (>1/1,000 and < 1/100)	Nasal passage irritation (stinging, itching) Sneezing Epistaxis
Gastrointestinal disorders	Rare (>1/10,000 <1/1,000)	Nausea
General disorders	Very rare (1/10,000)	Fatigue Weakness
Skin and subcutaneous tissue disorders	Very rare (1/10,000)	Rash Pruritus Urticaria

*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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@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: 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 Cmax 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

Nothing relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Disodium Edetate
Citric Acid Anhydrous
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

October 2018