Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rhinolast Hayfever 140 micrograms per spray, nasal spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Azelastine Hydrochloride 0.1 % w/v

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

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution.

Clear, colourless aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of seasonal allergic rhinitis (e.g. hay fever).

4.2 Posology and method of administration

Route of application is topical - nasal mucosa.

Adults
One application (0.14 ml) in each nostril twice daily (0.56 mg of azelastine hydrochloride).

Children
RHINOLAST HAYFEVER is not recommended for use in children aged 12 or below.

Duration
RHINOLAST HAYFEVER should not be used for longer than 4 weeks without a consultation with a doctor.

4.3 Contraindications

Proven allergy against azelastine hydrochloride.

4.4 Special warnings and precautions for use

None.

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 to far backwards, which may, in rare cases, lead to nausea. This occurs more frequently at the higher dose level.

Uncommon (0.1-1%) - 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, <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

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use; Anti-allergic agents, excluding corticosteroids

ATC Code: R01AC03

Allergospray Nasal Spray is an anti-allergic / antihistaminic agent.

Azelastine hydrochloride acts as an H_1-antagonist and consequently is an anti-allergic compound. Furthermore, in vivo studies in the guinea pig have shown that, in doses relevant for human therapy, azelastine hydrochloride also inhibits the bronchial constriction induced by leukotrienes and PAF.

It is due to these properties that, in animal experiments, azelastine hydrochloride also has been able to suppress the inflammation in the respiratory tract causing this hyper-reactivity. The significance of the findings obtained in animals for the therapeutic application of azelastine hydrochloride in humans is unclear.

In preclinical studies, inhibition of mast cell degranulation was shown in addition to the H_1-antagonistic effect and anti-inflammatory properties of azelastine mentioned above.

Data from clinical studies show that azelastine nasal spray has a faster onset of action than desloratadine tablets and nasally administered mometasone. A relief of nasal allergic symptoms is observed within 15 minutes after administration.

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
Disodium phosphate dodecahydrate
Sodium chloride
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years unopened.

Discard any remaining contents six month after first opening.

6.4 Special precautions for storage

Do not refrigerate.

6.5 Nature and contents of container

10ml polyethylene bottle with polypropylene cap and polyethylene seal, with accompanying pump, containing 5 ml of aqueous solution. (35 sprays)

10 ml glass bottle (brown; hydrolytic Type III) with pump attached, containing 5 ml of aqueous solution. (35 sprays)

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

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 Hayfever spray is now ready to use.

For separate bottle and pump
Open the bottle by unscrewing the cap. Place the spray pump nozzle in the bottle and screw the pump onto 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.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA2010/037/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 February 2001

Date of last renewal: 23 February 2006

10 DATE OF REVISION OF THE TEXT

February 2022