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).

Elderly
No dose adjustment is necessary.

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

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

4.4 Special warnings and precautions for use

None.

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 to 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.

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.
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

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^2 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^2 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

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

Cooper Consumer Health B.V.
Verrijn Stuartweg 60
Diemen
Noord-Holland
1112 AX
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA25506/006/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 23 February 2006

10 DATE OF REVISION OF THE TEXT

January 2026