SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rhinolast Allergy 0.1% w/v Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Solution containing 0.1% w/v azelastine hydrochloride

One actuation (0.137 ml) contains: 0.137 mg azelastine hydrochloride equivalent to 0.125 mg azelastine.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal spray

Clear, to almost colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of both seasonal allergic rhinitis (e.g. hay fever) and perennial allergic rhinitis in patients aged 6 years and over.

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

For children aged 6 years and older, one application (0.14 ml) in each nostril twice daily (0.56 mg of azelastine hydrochloride).

Elderly

No dose adjustment necessary for Rhinolast Allergy 0.1% w/v Nasal Spray.

Duration

Rhinolast Allergy 0.1 % w/v Nasal Spray should not be used continuously 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

Not to be used to relieve the symptoms of Upper Respiratory Tract Infection.

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.

Rarely, the patient may experience fatigue, dizziness or weakness due to the disease itself, or when using Rhinolast Allergy 0.1% w/v Nasal Spray. In these cases, the ability to drive and use machines may be impaired. Special attention should be paid to the fact that alcohol may enhance these effects.

4.8 Undesirable effects

Commonly, dysgeusia, a substance-specific unpleasant taste, may be experienced after administration (often due to incorrect method of application, namely tilting the head too far backwards during administration) which, in rare cases, may lead to nausea.

Adverse events are listed below by system organ class and frequency. Frequencies are defined as:

Very common (≥ 1/10);
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), not known (cannot be estimated from the available data).

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
Nervous system disorders	Dysgeusia (bitter/unpleasant taste)		Dizziness*	
Respiratory, thoracic and mediastinal disorders		Nasal discomfort (stinging, itching), Sneezing, Epistaxis		
Gastrointestinal disorders			Nausea	

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
Skin and subcutaneous tissue disorders				Rash, Pruritus, Urticaria
General disorders			Fatigue*, Weakness*	

* These adverse reactions occur very rarely and may also be caused by the disease itself (see also section 4.7).

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 the Yellow Card Scheme at: http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

After repeated oral administration, the mean Cmax steady state plasma levels were determined giving 3.9ng/ml for azelastine and 1.86ng/ml for desmethylazelastine after 2.2mg 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

Azelastine hydrochloride displayed no sensitizing potential in the guinea pig. Azelastine demonstrated no genotoxic potential in a battery of in vitro and in vivo tests, nor any carcinogenic potential in rats or mice.

In male and female rats, azelastine at oral doses greater than 3.0 mg/kg/day caused a dose-related decrease in the fertility index; no substance-related alterations were found in the reproductive organs of males or females during chronic toxicity studies.

Embryotoxic and teratogenic effects in rats, mice and rabbits (foetal death, growth retardation and an increased incidence of skeletal abnormalities) occurred only at maternal toxic doses (for example in mice and rats at doses of 68.6 mg/kg/day).

Effects in non-clinical studies were observed only at human equivalent doses considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose

Disodium edetate

Citric acid anhydrous

Disodium phosphate dodecahydrate

Sodium chloride

Purified water

6.2 Incompatibilities

None

6.3 Shelf life

Three years unopened, discard six months after opening

6.4 Special precautions for storage

Do not refrigerate

6.5 Nature and contents of container

Either a 10ml polyethylene bottle with polypropylene and polyethylene seals (containing 5ml solution), or a brown glass bottle with attached Valois pump containing 5ml Rhinolast Allergy 0.1% w/v Nasal Spray solution (36 doses).

6.6 Special precautions for disposal

Remove the protective cap. Before first using, squeeze down the collar several times until an even spray emerges. The Rhinolast Allergy 0.1% w/v Nasal Spray 5ml spray is now ready to use.

7 MARKETING AUTHORISATION HOLDER

Cooper Consumer Health B.V.,
Verrijn Stuartweg 60, 1112 AX Diemen,
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

PL 60682/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/05/2002

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12/09/2025