SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rhinolast Allergy 0.1% w/v Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Azelastine Hydrochloride 0.1% w/v

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).

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

Proven allergy against azelastine hydrochloride

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

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

The following frequencies of undesirable effects were reported:

Commonly (1 - 10 %), a substance-specific bitter 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.

Uncommonly (0.1 - 1 %), a mild, transient irritation of the inflamed nasal mucosa may occur with symptoms such as stinging, itching, sneezing and epistaxis.

In very rare cases (< 0.01 %), hypersensitivity reactions (such as rash, pruritus, urticaria) were reported.

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:

www.mhra.gov.uk/yellowcard

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

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

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

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

Mylan Products Ltd,

Station Close,

Potters Bar,

Hertfordshire,
EN6 1TL,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 46302/0083

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/05/2002

10 DATE OF REVISION OF THE TEXT

28/02/2019