PACKAGE INSERT

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SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME (and dosage form)

SINUMAX® ALLERGY NASAL SPRAY

COMPOSITION

Each ml of the microsuspension contains levocabastine hydrochloride equivalent to 0,5 mg levocabastine.

Preservatives: Benzalkonium chloride 0,015 % m/v and disodium edetate 0,015 % m/v.

Each spray (puff) contains approximately 50 µg levocabastine.

Excipients: disodium hydrogen phosphate anhydrous, hypromellose, polysorbate 80, propylene glycol, sodium dihydrogen phosphate monohydrate, purified water

PHARMACOLOGICAL CLASSIFICATION

A.5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION

Levocabastine is a long lasting selective histamine H_1-antagonist that is used for topical treatment of allergic disorder of the nasal mucosa. It has a prolonged elimination half-life of 30 - 40 hours.

After intranasal application, about 30 - 40 µg levocabastine per puff is absorbed.

Levocabastine reaches peak plasma levels about 3 hours after nasal administration.

Protein binding of levocabastine in plasma is approximately 55 %. The primary metabolite of levocabastine, an acylglucuronide, is produced by glucuronidation.

Levocabastine is predominantly excreted in the urine as unchanged substance (about 70 % of the absorbed dose). The plasma pharmacokinetics of nasal levocabastine are linear and predictable.

Typical systemic antihistaminic effects have been observed in human volunteers after oral administration of therapeutically effective doses of levocabastine following histamine provocation.

Special populations;

Elderly

In the elderly after multiple nasal administrations of 0,4 mg levocabastine, the terminal half-life of levocabastine was increased by 15 %, and the peak plasma level was increased by 26 %.

Renal impairment

After a single oral dose of 0,5 mg levocabastine in solution, the terminal half-life of levocabastine in moderate to severe renal impairment (Creatinine Clearance 10 - 50 ml/min) increased from 36 hours to 95 hours. Overall exposure to levocabastine based on AUC was increased by 56 %.

INDICATIONS

Short term symptomatic treatment of seasonal allergic rhinitis.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS

Since elimination of levocabastine is prolonged in patients with renal impairment, caution should be exercised when administering SINUMAX ALLERGY NASAL SPRAY to patients with renal impairment.

SINUMAX ALLERGY NASAL SPRAY lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol and other central nervous system depressants.

INTERACTIONS

There may be an interaction with alcohol if taken concomitantly with SINUMAX ALLERGY NASAL SPRAY.

The decongestant oxymetazoline may transiently reduce the absorption of nasal levocabastine.

Co-administration of the CYP3A4 inhibitors ketoconazole, itraconazole or erythromycin had no impact on the pharmacokinetics of intranasal levocabastine.

Intranasal levocabastine did not change the pharmacokinetics of loratadine.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

Small amounts of levocabastine occur in breastmilk.

DOSAGE AND DIRECTIONS FOR USE

SINUMAX ALLERGY NASAL SPRAY is available as a microsuspension and the bottle should be shaken before each application.

ADULTS AND CHILDREN OVER 5 YEARS: The usual dose is 2 puffs of SINUMAX ALLERGY NASAL SPRAY per nostril, twice daily for up to 8 weeks.

CHILDREN 6 MONTHS TO 5 YEARS: The usual dose is 1 puff of SINUMAX ALLERGY NASAL SPRAY per nostril, twice daily for up to 4 weeks.

Patients should be instructed to clear the nasal passages prior to administering the spray and to inhale through the nose during spraying. Before using the pump delivery system for the first time, the pump reservoir should be filled up by priming until a fine spray is delivered.

SIDE-EFFECTS

Clinical trial data:

Adverse drug reactions (ADRs) reported during clinical trials: ADRs are listed below by system organ class and frequency. Frequencies are defined as: Very common (≥1/10) and Common (≥1/100, <1/10).

Gastrointestinal disorders:

Common: Nausea

General disorders and administration site conditions:

Common: Fatigue, pain, irritation, dryness, burn, discomfort

Infections and infestations:

Common: Sinusitis

Nervous system disorders:

Very common: Headache

Common: Somnolence, dizziness

Respiratory, thoracic and mediastinal disorders:

Common: Pharyngolaryngeal pain, epistaxis, cough, nasal discomfort, nasal congestion

Postmarketing data:

Cardiac disorders

Palpitations, tachycardia

Eye disorders

Eyelid oedema

General Disorders and Administration Site Conditions

Malaise

Immune System Disorders

Anaphylaxis, hypersensitivity

Respiratory, Thoracic and Mediastinal Disorders

Broncospasm, dyspnoea, nasal oedema

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment is symptomatic and supportive.

Following accidental oral intake of the contents of the bottle, sedation may occur. The patient should be advised to drink a lot of non-alcoholic fluids in order to accelerate the renal elimination of SINUMAX ALLERGY NASAL SPRAY.

IDENTIFICATION

A white homogenous microsuspension.

PRESENTATION

SINUMAX ALLERGY NASAL SPRAY is available in 15 ml containers, containing 10 ml or 15 ml of SINUMAX ALLERGY NASAL SPRAY suspension.

STORAGE INSTRUCTIONS

Store at or below 25 ºC. Protect from light. Shake well before use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

X/5.7.1/230

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION.



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