RHINOFEX

MD Spray

Composition

Rhinofex MD Spray

Each 1 ml contains Dimetindene maleate 0.25mg & Phenylephrine (HCL) 2.5mg

Action

Combined drug containing in its composition 2 active components.

Phenylephrine is a symptomatic remedy, with topical application, by stimulating α1-adrenoreceptors of the venous vessels of the nasal mucosa, has a vasoconstrictive effect, eliminates edema of the nasal mucosa and airway sinuses.

Dimetindene is an antiallergic component, an antagonist of H1-histamine receptors, which does not reduce the activity of the ciliated epithelium of the nasal mucosa.

Pharmacokinetics

Rhinofex MD Spray is a topical drug. As a consequence, its activity does not correlate with the concentration of active substances in the blood plasma.

In case of accidental ingestion of the agent on the oral mucosa and subsequent absorption of Phenylephrine, the bioavailability reaches approximately 38%, the elimination half-life is 2.5 hours.

Indication

Rhinofex MD Spray is used as a symptomatic agent in the following conditions:

- Colds;
- Nasal congestion;
- Acute and chronic rhinitis;
- Allergic rhinitis;
- Acute otitis media (as an adjuvant therapy);
- Preoperative preparation and postoperative elimination of edema of the nasal mucosa and accessory sinuses.

Warnings and Precautions

like other sympathomimetic agents, Rhinofex should be used with caution in patients showing a strong reaction to adrenergic substances, as manifested by signs of insomnia, dizziness, tremor, cardiac arrhythmias or elevated blood pressure.

Rhinofex should not be used continuously for more than 7 days. Prolonged or excessive use may induce tachyphylaxis and rebound congestion (rhinitis medicamentosa).

As with other topical vasoconstrictors, do not exceed the recommended dosage; excessive use may lead, especially in small children and in the elderly, to systemic effects of vasoconstrictors.

Caution is recommended in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus and in case of administration in patient with bladder neck obstruction (eg. prostatic hypertrophy).

Due to the presence of the H1 anti-histamine Dimetindene maleate, Rhinofex should be used with caution in patients suffering from epilepsy.

Pediatric population:

Is not recommended in children below 6 years of age.

Fertility, pregnancy and lactation

Pregnancy
There are no studies regarding the use of Phenylephrine and Dimetindene maleate during pregnancy. in view of the potential systemic vasoconstrictor effect of Phenylephrine, it is however advisable to take the precaution of not using Rhinofex during pregnancy.

Breastfeeding
There are no studies regarding the use of Phenylephrine and Dimetindene maleate during lactation. it is advisable to take the precaution of not using Rhinofex during breast-feeding.

Fertility
There are no adequate data for the effects of Phenylephrine and Dimetindene maleate on fertility in humans. Based on animal studies, there are no indications for adverse effects on fertility following exposure to Dimetindene. There are no adequate experimental animal data regarding the effect of Phenylephrine on fertility.

Adverse Reactions
Rhinofex is usually well tolerated.

Adverse reactions are listed below, by system organ class and frequency:
Respiratory, thoracic and mediastinal disorders
Rare: Nasal discomfort, nasal dryness, epistaxis
General disorders and administration site condition
Rare: Application site burning

Drug Interactions
Rhinofex MD Spray is not recommended for use in combination with monoamine oxidase inhibitors (including if the drug was taken in the previous 14 days).

The vasoconstrictor with special caution is prescribed for patients taking antihypertensive drugs and tricyclic antidepressants.

Contraindications
- Hypersensitivity to Phenylephrine, Dimetindene maleate or to any of the components.
- Patients who are taking or have taken monoamine oxidase inhibitors (MAO's) within the previous 14 days.
- Patients with atrophic rhinitis.
- Patients with narrow angle glaucoma.

Dosage & Administration
This medicine is not usually intended for administration to children and infants under 6 years of age.

Before irrigation of the nasal cavity, it is recommended to thoroughly clean the nasal passages. Adults and children who reached the age of 6, it is recommended to use the drug 3-4 times a day, 1-2 injections. The bottle should be kept strictly vertical when injecting the nebulizer into the nasal cavity. After injecting the spray, you need to inhale slightly through the nose. The course of treatment should not exceed 7 days.

<u>Method of administration</u>
The protective cap should be removed. Before the first application, several pumping motions should be performed until an even spray appears in the air. At subsequent applications the dosing spray will then be ready for instant use.

The patient should insert the nozzle into the nostril and press once firmly on the spray head. Then withdraw the nozzle should be withdrawn before releasing pressure. Optimal distribution of the spray is achieved by breathing in a little air through the nose during the spraying process. The protective cap should be replaced after use.

The dosing spray ensures that Rhinofex solution is well distributed over the surface of the nasal mucosa. The standardized valve with which it is fitted permits accuracy of dosage and precludes the possibility of unintentional overdosage.

Overdose

Overdose may cause sympathomimetic effects such as palpitation, ventricular premature contractions, occipital headache, trembling or tremors, slight tachycardia, increased blood pressure, excitation, sleeplessness and pallor. it may also cause mild sedation, dizziness, tiredness, stomach ache, nausea, vomiting and mild anticholinergic effects.

The use of charcoal and possibly a laxative may be indicated in young children. For older children and adults, the administration of large quantities of fluid is usually sufficient. Phenylephrine induced hypertension may be relieved by administration of an alpha-adrenergic blocking agent.

Presentation

Rhinofex MD Spray

Microdoser bottle of 15 ml