
Regulatory Affairs

Vibrocil Nasal Drops

Dimetindene maleate 0.025% + Phenylephrine base 0.25%

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1. NAME OF THE MEDICINAL PRODUCT

Vibrocil

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Phenylephrine 2,5 mg/ml and Dimetindene maleate 0,25mg/ml.

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Vibrocil Nasal Drops

4. CLINICAL PARTICULARS**4.1. Therapeutic indications**

For short-term symptomatic treatment of nasal congestion and itching, such as colds, sinusitis, allergic rhinitis and other upper respiratory diseases.

As adjuvant therapy for otitis media.

Preparation for surgical interventions in the nasal area and elimination of edema of the nasal mucosa and paranasal sinuses after surgical interventions in this area.

If after 3 days there is no improvement or symptoms worsen, you should consult a doctor.

4.2. Posology and method of administrationDosing regimen

Do not exceed the prescribed dose and increase the frequency of use of the drug.

The lowest doses and the minimum duration of administration necessary to achieve the effect should be used.

Adults

3-4 drops in each nasal passage 3-4 times a day.

Children*Children under 2 years old*

Vibrocil is not recommended for use in children under 2 years of age.

Children from 2 to 6 years old

Children aged 2 to 6 years (under the supervision of adults) apply 1-2 drops in each nasal passage 3-4 times a day.

Children over 6 years old

The dosage regimen is the same as for adult patients. Apply under adult supervision.

Method of administration:

Before use, thoroughly clean the nasal passages (for example, blow the nose). Bury in each nasal passage, slightly tilting your head back. This position of the head is maintained for a short period of time so that the drops can be distributed. Care must be taken to avoid getting drops in the eyes. The pipette should be cleaned and dried before screwing it back onto the vial.

In order to avoid the possible spread of infection, do not pass the vial of Vibrocil, nasal drops, to other persons.

4.3. Contraindications

Hypersensitivity to the components of the drug.

Vibrocil is contraindicated:

- with atrophic rhinitis (including with foul-smelling discharge - ozena);
- in patients who are taking or have taken monoamine oxidase (MAO) inhibitors in the previous 14 days;
- in patients with angle-closure glaucoma;
- in patients after transsphenoidal removal of the pituitary gland (either transnasal or transoral surgery with exposure of the dura mater).

4.4. Special warnings and precautions for use

Caution should be exercised when using Vibrocil drops in patients with hypersensitivity to sympathomimetics, which is manifested by the development of insomnia, dizziness, tremors, cardiac arrhythmias and increased blood pressure.

Vibrocil should not be used for more than 3 consecutive days. If symptoms persist or the condition worsens, a doctor should be consulted. Prolonged use or the use of high doses of the drug can cause tachyphylaxis, flushing due to withdrawal syndrome or drug-induced rhinitis.

As with all topical vasoconstrictors, the recommended doses should not be exceeded. This applies especially to young children and the elderly, in whom too high a dosage can lead to systemic adverse reactions. Vibrocil drops should be used with caution in patients suffering from arterial hypertension, cardiovascular diseases, hyperthyroidism, obstruction of the bladder neck (for example, prostate adenoma), and diabetes mellitus. Patients with epilepsy should use Vibrocil drops with caution due to the content of the histamine H1 receptor antagonist dimethindene maleate.

Vibrocil drops are not recommended for children under 2 years of age. Children aged 2 to 12 years should use the drug under adult supervision.

Benzalkonium chloride, which is part of the drug, can cause irritation and swelling of the nasal mucosa, especially with prolonged use.

4.5. Interactions with other medicinal products and other forms of interaction

Phenylephrine is contraindicated in patients taking monoamine oxidase inhibitors or who have received them within 2 weeks prior to the start of the use of Vibrocil drops.

The use of monoamine oxidase inhibitors and sympathomimetic amines, such as phenylephrine, can lead to the development of a hypersensitivity reaction (see section "Contraindications").

In patients taking tri- and tetracyclic antidepressants or antihypertensive drugs such as beta-blockers, vasoconstrictor drugs should be used with caution, since concomitant use may increase the hypertensive effect of phenylephrine and lead to the risk of developing hypertension or other adverse reactions from the cardiovascular side systems.

4.6. Pregnancy and lactation

Pregnancy

Studies on the use of phenylephrine and dimethindene maleate during pregnancy in women have not been conducted. As a precautionary measure, it is not recommended to use the drug during pregnancy.

Lactation

Studies on the use of phenylephrine and dimethindene maleate during breastfeeding have not been conducted. Phenylephrine and dimethindene maleate can pass into breast milk. As a precautionary measure, it is not recommended to use the drug during breastfeeding.

Fertility

No fertility data available.

4.7. Effects on ability to drive and use machines

None

4.8. Undesirable effects

Information on adverse reactions is presented in accordance with the classes of organs and systems, and the frequency of occurrence in the following categories: very often ($\geq 1/10$), often ($\geq 1/100$, but $< 1/10$), infrequently ($\geq 1/1000$, but $< 1/100$), rare ($\geq 1/10000$, but $< 1/1000$), very rare ($< 1/10000$). Within each group, adverse reactions are presented in order of decreasing severity.

Respiratory, thoracic and mediastinal disorders:

Rare: Nasal discomfort, dry nose, epistaxis.

General disorders and reactions at the injection site:

Rarely: burning at the site of application.

4.9. Overdose

An overdose of Vibrocil may cause sympathomimetic and anticholinergic effects, including palpitations, ventricular extrasystoles, mild sinus tachycardia, hypertension, occipital headaches, tremors or tremors, mydriasis, confusion,

pallor, agitation, hallucinations, convulsions, insomnia, and sedation, fatigue, coma, abdominal pain, nausea and vomiting.

After accidental ingestion of Vibrocil, no severe symptoms have yet been observed. Accidental ingestion of up to 20 mg of dimethindene has not resulted in severe symptoms.

In children, after ingestion of the entire vial of Vibrocil (15 ml), special measures are not required.

Since there is no data for taking more than 20 mg of dimethindene, medical supervision is indicated, and after consultation with a clinical expert or a poison information center, a single dose of activated charcoal is indicated.

Severe cases of agitation and convulsions should be treated with benzodiazepines. The use of antidotes should be discussed with a clinical expert or poison information centre: central anticholinergic symptoms can be treated with physostigmine. Hypertension caused by peripheral sympathomimetic stimulation that does not respond well to benzodiazepines can be treated with an alpha-blocker.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group

decongestants and other topical nasal preparations. ATC: R01AB01

Mechanism of action

Vibrocil reduces nasal discharge and helps to cleanse the nasal passages without disturbing the physiological functions of the ciliated epithelium and nasal mucosa. Phenylephrine is a sympathomimetic drug, when applied topically it has a moderate vasoconstrictive effect (due to stimulation of alpha-1-adrenergic receptors located in the venous vessels of the nasal mucosa), eliminates swelling of the nasal mucosa and its paranasal sinuses.

Dimetindene is a well-tolerated antiallergic drug - an antagonist of histamine H1 receptors, which is effective in small doses.

5.2. Pharmacokinetic properties

Vibrocil is intended for topical use, and its activity does not depend on the concentration of active substances in the blood plasma.

In case of accidental ingestion, phenylephrine has a reduced bioavailability (approximately 38%) due to metabolism during the initial intake in the intestine and liver. The apparent half-life of phenylephrine is about 2.5 hours.

The systemic availability of dimethindene in oral solution is about 70%. The apparent half-life of dimethindene is about 6 hours.

Data on absorption, distribution, biotransformation and elimination are not available.

5.3 Preclinical safety data

Routine studies of safety pharmacology, repeated dose toxicity, genotoxicity, reproductive toxicity, and developmental toxicity did not reveal any specific risk.

6. PHARMACEUTICAL PARTICULARS**6.1. List of excipients**

Disodium phosphate anhydrous
Citric acid monohydrate
Sorbitol
Benzalkonium chloride
Terpene-free lavender essential oil
Purified water

6.2. Incompatibilities

Not applicable.

6.2. Shelf life

3 years.

6.4. Special precautions for storage

Store at a temperature not exceeding 25 °C. Keep out of the reach of children.

6.5. Nature and contents of container

15 ml in a dark glass bottle with a pipette screw cap. The bottle, along with instructions for use, is placed in a cardboard box.

7. MARKETING AUTHORISATION HOLDER

JSC «GlaxoSmithKline Healthcare», Russia.

Address: 123112, Russia, Moscow, Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor.

7.2 Manufacturer

GSK Consumer Healthcare SARL, Switzerland.

Route de l'Etraz, 1260 Nyon, Switzerland.

10. DATE OF REVISION OF THE TEXT

09.11.2022

