

Vibrocil[®]**Rhinitis****Composition***Nasal drops, nasal spray, microdoser*

Active constituents: Dimetindeni maleas 0.25 mg, Phenylephrinum 2.5 mg. Aromatica, Conserv.: Benzalkonii chloridum, Excipiens ad solutionem pro 1 ml.

Nasal gel

Active constituents: Dimetindeni maleas 0.25 mg, Phenylephrinum 2.5 mg. Aromatica, Conserv.: Benzalkonii chloridum, Excipiens ad gelatum pro 1 g.

Properties/Effects

Vibrocil clears the nose and dries up discharges while respecting the physiology of the vibratile cilia and the nasal mucosa. Phenylephrine is a sympathomimetic amine. Due to its selective action on α_1 -adrenergic receptors of the cavernous venous tissue of the nasal mucosa, phenylephrine is a gentle vaso-constrictor which allows rapid and durable decongestion of the nasal fossae.

Dimethindene maleate, a histamine antagonist acting on the H_1 receptors, is an antiallergic product which is effective at low doses and is well tolerated.

Pharmacokinetics

This product is intended for local application, and its activity is not correlated with the blood concentration of its active ingredients.

Indications/Therapeutic use

Common colds, acute and chronic rhinitis, seasonal (hay fever) and non-seasonal allergic rhinitis, acute and chronic sinusitis, pre- and postoperative care, adjuvant in cases of acute otitis media.

Vibrocil gel is especially useful in cases of dryness of the nasal mucosa, in the presence of crusts or in the sequelae of nasal trauma and to keep the nose clear for the night.

Dosage/Directions for use*Nasal drops*

After blowing the nose carefully, apply 3 to 4 times a day, in each nostril.

Children from 1 to 6 years: 1 to 2 drops.

Children over 6 years and adults: 3 to 4 drops.

The application should preferably be made in a seated position. Immediately after each instillation, tilt the head back to promote penetration.

Nasal spray

Children over 6 years and adults: after blowing the nose carefully, apply 1 to 2 sprays in each nostril, 3 to 4 times a day.

Hold the atomizer vertically, introduce the tip into one nostril and hold the other one closed, squeeze the container sharply and make sure to withdraw it each time before releasing the pressure.

Microdoser

Children over 6 years and adults: 1 to 2 sprays in each nostril, 3 to 4 times a day (one spray provides a mean of 140 mg).

Proceed as follows:

1. Blow the nose carefully.
2. Remove the protective cap.
Before using for the *very first time*, operate the microdoser several times to prime it. It is then ready for subsequent use.
3. Insert the microdoser into one nostril and press it while breathing in through the nose at the same time. Repeat this operation in the other nostril.
4. Replace the protective cap.



Remove the protective cap.



Hold the microdoser exactly as shown in the diagram. Press and breathe in at the same time.

Nasal gel

Children over 6 years and adults: after blowing the nose carefully, apply Vibrocil gel as deeply as possible into each nostril, 3 to 4 times a day.

One application at bedtime keeps the nose clear for the night.

Restrictions on use**Contraindications**

Hypersensitivity to any of the constituents.

Like other vasoconstrictors, phenylephrine is contraindicated in cases of simple atrophic rhinitis, atrophic rhinitis with foetid discharges (ozena) and in patients taking MAO inhibitors or who have received them during the previous two weeks.

Precautions

Vibrocil must not be used continuously for more than 1 week. If the symptoms persist, consult a doctor. Its prolonged or excessive use may lead to tachyphylaxis, rebound congestion or drug-induced rhinitis.

As with all topical vasoconstrictors, do not exceed the pre-scribed doses, particularly in babies, young children and elderly persons: excessive use may lead to the appearance of systemic defects, especially in young children and the elderly.

Excessive doses must also be avoided in the case of hypertension or other cardiovascular diseases, hyperthyroidism or narrow angle glaucoma.

Like all products containing a topical vasoconstrictor, Vibrocil must be used cautiously in the case of excessive reactions to sympathomimetics, expressed by insomnia or dizziness. Use nasal drops for infants and children under 6 years.

Pregnancy, breast feeding

Studies are not available in pregnant women, nursing mothers or animals. Because of this, Vibrocil should not be administered during pregnancy, except in case of absolute necessity.

Undesirable side effects

A local and transient sensation of smarting or dryness of the nose may be observed in rare cases.

Interactions

Like all vasoconstrictors, phenylephrine is contraindicated in patients treated with MAO inhibitors, or who have received them in the previous two weeks.

Caution is required when taking tricyclic antidepressants or antihypertensives such as beta-blockers.

Overdosage

The accidental ingestion of Vibrocil by small children has never produced any serious side effects.

The majority of cases were asymptomatic but tiredness, stomachache, mild tachycardia, increased blood pressure, excitation, insomnia and pallor have sometimes been reported. There is no specific antidote in the case of overdosage with a combination of an antihistamine and a vasoconstrictor. Gastric lavage is not required in principle, even after the ingestion of a full bottle (15 ml).

In young children, the administration of activated charcoal and possibly a laxative may be indicated. For older children (over 6 years) and adults, the administration of a large quantity of fluid is usually sufficient.

Further remarks

Storage: Do not store above 30 °C for all forms except for 10 ML spray Store below 25 °C. Protect from light and heat. The medicine may be used only up to the date «EXP» shown on the package.

Packaging:

Nasal drops: 15 ml.

Nasal spray: 10 ml.

Microdoser: 15 ml.

Nasal gel: 12 g.

**Novartis Consumer Health SA
Nyon Switzerland****Information updated**

October 2003.

(THIS IS A MEDICAMENT)

- a. Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- b. Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- c. The doctor and the pharmacist are experts in medicine, its benefits and risks.
- d. Do not by yourself interrupt the period of treatment prescribed.
- e. Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

E-AR 909806 – 147449

NOVARTIS