

## **1. Vibrocil Microdoser**

### **2. Composition**

*Active ingredients:* Dimetindene maleate 0.025% W/V, Phenylephrine 0.25% W/V.

### **3. Pharmaceutical form and amount of active ingredient per unit**

*Microdoser*

1 mL contains: Dimetindene maleate 0.25 mg, phenylephrine 2.5 mg.

1 spray (=0.14 mL) contains 0.035 mg dimethindene maleate and 0.35 mg phenylephrine.

A standardized valve enables exact dosing (mean value: 140 µL solution per spray).

### **4. Indications/Applications**

#### **4.1 Indication:**

Symptomatic treatment of common cold, nasal congestion, acute rhinitis, seasonal (hay fever) and non seasonal allergic rhinitis, acute sinusitis. Adjunctive therapy in case of acute otitis media.

#### **4.2 Dosing regimen/use**

Do not exceed the indicated dosage and frequency of use.

The lowest effective dosage should always be used, and the treatment kept as short as possible.

#### **Children older than 6 years (under adult supervision) and adults:**

1 to 2 sprays into each nostril 3 to 4 times a day.

#### **Using the microdoser**

1. Thoroughly clean your nose (e.g. by blowing it) before use.
2. Be careful not to get the spray into your eyes.
3. Remove the protective cap. Before first use, actuate the pump 5 times to prime it. The microdoser is now ready for further use. If the product has not been used for some time, the pump must be actuated 5 times again before use.
4. Insert the microdoser into one nostril and breathe in through your nose as you spray once, pressing down firmly on the pump. Repeat the process in the other nostril.
5. Wipe and dry the nozzle tip before putting the protective cap back on.

Do not share your bottle of Vibrocil metered-dose spray with other people to avoid any possible spread of infection.

### **4.3 Contraindications**

Hypersensitivity to one of the active substances (phenylephrine, dimetindene maleate) or one of the excipients listed in section 6.1.

Contraindicated in:

- simple atrophic rhinitis, ozena (rhinitis atrophicans cum foetore)
- patients who are on MAO inhibitors or who have taken them in the preceding two weeks.
- patients with narrow-angle glaucoma as well as
- after transsphenoidal hypophysectomy (or after transnasal or transoral surgical procedures in which the dura mater is exposed).

### **4.4 Special warnings and precautions for use**

Patients with hypersensitivity to sympathomimetics, manifested as insomnia, dizziness, tremors, cardiac arrhythmia or arterial hypertension, should use sympathomimetics such as Vibrocil with caution.

Vibrocil should not be used continuously for more than 7 days. If symptoms persist or worsen, medical advice should be sought. Long-term or high-dose use can result in tachyphylaxis, congestion due to a rebound effect or drug-induced rhinitis.

As with any topical vasoconstrictors, the prescribed dose must not be exceeded; this applies in particular to small children and elderly patients, in whom too high a dosage may cause systemic effects.

Caution is advised in patients with hypertension, cardiovascular diseases, hyperthyroidism, diabetes and bladder neck obstruction (e.g. prostatic hypertrophy).

Vibrocil should be used with caution in patients with epilepsy because of dimethindene maleate which is an H<sub>1</sub> antihistamine dimethindene.

#### **Children**

*Vibrocil microdoser* is not recommended for children under 6 years of age, Vibrocil should be used under adult supervision.

#### **Excipients:**

This medicine contains 0.015 mg of Benzalkonium chloride in each actuation of 0.140 mL, which is equivalent to 0.106 mg/mL ( $\approx 475\ 000\ \text{mg} / 4500\ 000\ \text{mL}$  for a batch)

Benzalkonium chloride can cause irritation or swelling of the nasal mucose, especially during prolonged use.

## **4.5 Interactions**

### ***Monoamine oxidase inhibitors***

Phenylephrine is contraindicated in patients who are currently taking MAO inhibitors, or who took them in the preceding two weeks. The use of MAO inhibitors and sympathomimetic amines such as phenylephrine can trigger a hypertensive reaction (see “Contraindications”).

### ***Tricyclic and tetracyclic antidepressants***

Vasoconstrictors should be used with caution in patients taking tricyclic and tetracyclic antidepressants; concomitant administration may potentiate the hypertensive effects of phenylephrine.

### ***Beta blockers and other antihypertensive drugs***

Vasoconstrictors should be used with caution in patients taking beta blockers or other antihypertensive drugs. Phenylephrine can reduce the effects of beta blockers and other antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased; use is therefore not recommended.

## **4.3 Pregnancy, lactation**

### ***Pregnancy***

There are no studies on the use of phenylephrine dimethindene in pregnant women. Vibrocil should therefore not be used during pregnancy as a precaution.

### ***Breastfeeding***

There are no studies on the use of phenylephrine and dimethindene maleate during breastfeeding. Phenylephrine and dimethindene maleate may pass into human breast milk. As a precautionary measure, Vibrocil should not be used during breastfeeding.

### ***4.4 Effect on the ability to drive and use machines***

No data available.

### ***4.5 Adverse effects***

The adverse effects are classified according to MedDRA system organ class and frequency. The information on the type and frequency of adverse effects comes mainly from older studies from the 1970s and 1990s.

Frequencies are defined as follows: Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ). Within

the individual frequency groups, the undesirable effects are arranged in descending order of severity.

*Respiratory , thoracic and mediastinal disorders*

*Rare:* Nasal symptoms, nasal dryness, epistaxis.

*General disorders and administration site conditions*

*Rare:* Burning sensation at the application site.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/>

#### **4.6 Overdose**

##### ***Signs and symptoms***

An overdose of Vibrocil may trigger sympathomimetic and anticholinergic effects including palpitations, ventricular extrasystoles, mild sinus tachycardia, hypertension, occipital headache, tremor, mydriasis, drowsiness, pallor, agitation, hallucination, seizures, insomnia, but also sedation, fatigue, coma, abdominal pain, nausea and vomiting.

To date, no severe symptoms have been observed after accidental ingestion of Vibrocil. Accidental ingestion of up to 20 mg dimethindene did not cause severe symptoms.

##### ***Treatment***

In children who ingest up to a whole bottle of Vibrocil (15 mL), no special measures are required.

Since no data are available on the ingestion of more than 20 mg dimethindene, medical supervision is indicated as well as , administration of a single dose of activated charcoal after consulting with a clinical expert or toxicology information center.

Severe restlessness and seizures should be treated with a benzodiazepine. The use of the following antidotes should be discussed with a clinical expert or Poisons Information Center. Hypertension that is triggered by peripheral sympathomimetic stimulation and that does not respond adequately to benzodiazepines can be treated with an alpha blocker.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Properties/effects**

ATC code: R01AB01

#### *Mechanism of action*

Vibrocil clears the nose and stops runny nose without affecting the physiological function of the cilia of the nasal mucosa. Phenylephrine is a sympathomimetic amine. Due to its selective effect on the  $\alpha$ -adrenoreceptors of the erectile venous tissues of the nasal mucosa, phenylephrine is a mild vasoconstrictor that quickly and lastingly relieves the swelling in the nasal passages.

Dimethindene maleate, a histamine antagonist that binds to H1 histamine receptors, is a well-tolerated antiallergic agent that is effective at low doses.

#### *Pharmacodynamics*

No further information.

#### *Clinical efficacy*

No further information.

### **5.2 Pharmacokinetics**

This medicinal product is indicated for local administration. There is no correlation between its efficacy and the blood levels of active substances.

If ingested accidentally, the bioavailability of phenylephrine is reduced (by approx. 38%) due to the first pass effect in the intestine and liver. The elimination half-life is approximately 2.5 hours.

The systemic availability of dimethindene in oral solutions is approximately 70%. The elimination half-life is approximately 6 hours.

#### *Absorption*

No data.

#### *Distribution*

No data.

#### *Metabolism*

No data.

#### *Elimination*

No data

### **5.3 Preclinical data**

No preclinical data relevant for the use of this medicinal product are available.

## **6 Other information**

### **6.1 Excipients:**

Sorbitol, Disodium Phosphate anhydrous, Citric Acid Monohydrate, Oil of lavender terpenless, Benzalkonium chloride.

### **6.2 Shelf life**

The expiry date of the product is indicated on the packaging materials

### **6.3 Storage**

Keep out of the sight and reach of children.

*Vibrocil microdoser*: Store below 25°C and protect from light and heat.

### **6.4 Packaging**

Vibrocil Microdoser 15 mL. polyethylene bottle with nosepiece with a protection cap.[D]77.

## **7. Marketing authorization number**

058-91-27319-00

## **8. Marketing authorization holder and importer**

Haleon CH IL Ltd

25 Basel ST., P.O.B 3256, Petach Tikva, 4951038, Israel.

## **9. Last revised**

Revised in December 2024.