PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Vibrocil Microdoser 0.25% w/v + 0.025% w/v

Metered-dose nasal spray

Active ingredients and their quantity in a dosing unit:

Dimethindene Maleate	**0.025% W/V**
Phenylephrine	**0.25% W/V**

Inactive ingredients and allergens in the preparation, please see section 6 and section 2 under the title "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.

1. What is the medicine intended for?

Vibrocil Microdoser is intended for temporary relief of nasal congestion and common cold, acute rhinitis, seasonal allergic rhinitis (hay fever), non-seasonal allergic rhinitis and acute sinusitis. Vibrocil Microdoser is also used as an adjunctive therapy for otitis media (inflammation of the middle ear).

Therapeutic class:

Dimethindene maleate – an anti-allergic agent.

Phenylephrine – a sympathomimetic agent, a capillary constrictor.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other components the medicine contains (please see section 6 and section 2).
- You are taking or have taken during the last 14 days antidepressants of the monoamine oxidase inhibitors group (MAO inhibitors).
- You have Atrophic Rhinitis/Ozena that has caused your nasal mucous membranes to become thinner.
- You have narrow angle glaucoma.
- You have undergone resection of the pituitary gland or surgery via the nose or the mouth in which the hard, outermost membrane of the central nervous system (dura mater) is penetrated.

Special warnings regarding the use of the medicine

Before treatment with Vibrocil Microdoser, inform the doctor if you have:

- High blood pressure, a cardiovascular disease
- Overactive thyroid
- Diabetes (high or low blood sugar levels)
- Epilepsy
- Difficulty during urination (e.g., enlarged prostate)
- You are taking antihypertensives (e.g., beta blockers), antidepressants (monoamine oxidase inhibitors (MAO inhibitors), or tricyclic and tetracyclic antidepressants), medicines for Parkinson's disease (see section 2 under "Do not use this medicine if:")

Vibrocil Microdoser may cause sleep disturbances, tiredness and tremor in people who are sensitive.
Vibrocil Microdoser is not intended for use in the mouth or the eyes.

Inform the doctor or pharmacist if you have other diseases or allergies.

Children and adolescents
This product is intended for children above 6 years of age.
In children up to 12 years of age, the product should be used with an adult's supervision.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist, especially if you are taking:

- Antidepressants of the monoamine oxidase inhibitors group (MAO inhibitors) or if you stopped taking these medicines during the last 14 days.
- Tricyclic and tetracyclic antidepressants.
- Antihypertensives of the beta blocker group.

Pregnancy, breastfeeding and fertility
Avoid using Vibrocil Microdoser if you are pregnant or breastfeeding, as the effects of the medicine in this population are unknown. The active ingredients may pass into breastmilk.

Driving and operating machinery
Vibrocil Microdoser does not affect the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine
The medicine contains 0.015 mg of benzalkonium chloride in each spray.
Benzalkonium chloride may cause irritation and swelling of the nasal mucosa, especially with prolonged use.

Additional warnings
Similar to other cold medicines that contain a vasoconstrictor, Vibrocil Microdoser may cause sleeplessness, drowsiness and tremor in people who are sensitive to this.
Vibrocil Microdoser is not intended for use in the mouth or the eyes.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

- **The generally accepted dosage is:**

Children above 6 years of age and adults: 1-2 sprays in each nostril, 3-4 times a day.
Do not exceed the recommended dose.

Duration of treatment
Do not use Vibrocil Microdoser for more than 7 consecutive days. If there is no improvement after 7 days, or if the symptoms worsen, consult with the doctor. Prolonged or excessive use may cause chronic inflammation in the nasal mucous membranes (rhinitis medicamentosa).

Use the lowest effective dose for the shortest treatment duration possible.
Method of use:
For nasal use, do not swallow.

1. Clear your nose before use (e.g., by blowing it).
2. Take care not to spray the preparation into your eyes.
3. Remove the protective cap. Before first use, prime the pump by pressing it several times. The preparation is now ready for use.
4. Insert the nozzle into the nostril and press it while inhaling through the nose. Repeat this procedure in the other nostril. Replace the protective cap.

Do not share your Vibrocil Microdoser spray with other people to prevent infection.

Use the preparation according to the instructions in this leaflet or according to the doctor's instructions. If you feel that the effect of the medicine is too weak or too strong, consult with the doctor or pharmacist.

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or the emergency room of a hospital immediately and take the package of the medicine with you.

If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Vibrocil Microdoser may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Rare side effects – side effects that occur in 1-10 out of 10,000 users: transient dryness and burning sensation in the nose, nose bleeding.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 30°C. Protect from light and heat.
- To be used within one month after first opening.

6. Additional information

- In addition to the active ingredients the medicine also contains:
  Sorbitol, Disodium phosphate anhydrous, Citric acid monohydrate, Oil of lavandin terpeneless, Benzalkonium chloride, Purified water.
- What does the medicine look like and what are the contents of the package – Vibrocil Microdoser is a clear-yellow solution in a 15-mL bottle of metered-dose spray.
- Marketing authorization holder and importer: GSK Consumer Healthcare Israel Ltd., P.O. Box 3256, Petah Tikva.
- Manufacturer: GSK Consumer Healthcare SARL, Route de l'Etraz 1260, Nyon, Switzerland.
- Revised in March 2022 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 589127319