PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) – 1986
This medicine is to be supplied without doctor's prescription

Vibrocil Microdoser

NOVARTIS

Active ingredients and their quantities in dosage unit:
Each 100 ml contains:
Dimetindene Maleate 0.025gr
Phenylephrine Base 0.250gr

For a list of inactive ingredients please see section 6.

Read this package insert carefully in its entirety before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, refer to the doctor or the pharmacist.

This medicine is to be supplied without doctor's prescription. (Vibrocil Microdoser is intended for adults and children over 6 years of age. Under this age refer to the doctor).

The medicine should be used in a proper manner. For more information consult a pharmacist. Refer to the doctor if the signs of the illness (symptoms) get worse or do not improve after 7 days.

1. What is this medicine intended for

Vibrocil is intended for temporary relief of nasal congestion and cold, acute rhinitis, seasonal allergic rhinitis (hay fever) and non-seasonal allergic rhinitis and acute sinusitis. Vibrocil acts as adjuvant therapy in middle-ear infection.

Therapeutic group:
Dimetindene maleate – an antihistamine
Phenylephrine - a capillary constrictor

2. Before using this medicine

Do not use this medicine if:
- You are sensitive (allergic) to the active ingredients or to any of the other ingredients that this medicine contains.
- You are taking a monoamine oxidase inhibitors (MAOI) antidepressant (for depression) or have taken such a medicine during the last 14 days.
- You suffer from chronic rhinitis which has caused thinning of the nasal mucosal tissues.

Special warnings regarding the use of this medicine
Before using Vibrocil, tell your doctor if you suffer from: heart disease, high blood pressure, hyperthyroidism, narrow angle glaucoma.

Do not use Vibrocil for more than 7 consecutive days. If the symptoms persist, consult the doctor. Prolonged or excessive use may result in recurrence or exacerbation of nasal congestion. Such conditions may lead to inflammation of the nasal mucous membranes, thus causing rhinitis due to the use of this medicine.

Do not exceed the recommended dose, especially in young children and elderly patients.

Vibrocil is not intended for use in the eyes or mouth.

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, inform your doctor or pharmacist. In particular inform the doctor or the pharmacist if you are taking:
Monoamine oxidase inhibitors (for depression) or within 14 days from stopping treatment with them, antidepressants of the tricyclic type, antihypertensives of the beta blockers type.

Pregnancy and breastfeeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, you should consult a doctor before starting to take this medicine, since the effects of the medicine in this population are unknown.

Driving and using machines
Vibrocil does not affect the ability to drive or to use machines.

3. How should you use the medicine?

You should check with the doctor or the pharmacist if you are unsure.

- **The recommended dose** is usually:
  Children 6-12 years of age (under supervision of an adult): 1-2 sprays in each nostril, 3-4 times daily.
  Adolescents over 12 years of age and adults: 1-2 sprays in each nostril, 3-4 times daily.

This medicine is not recommended for use in children below the age of 6 years.

Do not use Vibrocil for more than 7 consecutive days.

Do not exceed the recommended dose.

Directions for use:

Remove the protective cap. Before the first application, perform several pumping motions in the air, in order to prime the microdoser. Afterwards, it is ready for use.

Blow your nose. Insert the nozzle into a nostril and press it firmly once, while inhaling. Be sure to withdraw the nozzle from the nostril before releasing the pressure. Repeat the same procedure in the other nostril.

Replace the protective cap.

If you have accidentally taken a higher dose or if the medicine has been swallowed, contact a doctor or a pharmacist immediately.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

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

4. Side effects

As with any medicine, Vibrocil may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Uncommon side effects (1:1000): dry nose, burning at the site of spraying.

If any side effect becomes worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

5. How to store the medicine?

- Avoid poisoning! This medicine and all other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed by 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.
- Use within 1 month after opening the medicine for the first time.

6. Additional information

- In addition to the active ingredients the medicine also contains:
  Benzalkonium chloride, Disodium phosphate anhydrous, Citric acid monohydrate, Sorbitol, Oil of lavandin terpenless, Purified water.
- What does the medicine look like and what are the contents of the package – Vibrocil is a clear - yellow solution supplied in a 15 ml bottle with a metered dosing device and a nasal nozzle with a cover.
- Registration holder name and address: NCH Ltd., 14 Hamefalsim st., Petach-Tikva.
- Manufacturer: Novartis Consumer Health, Switzerland.
- This leaflet was checked and approved by the Ministry of Health in: January 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 589127319