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**PATIENT PACKAGE, INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

This medicine is dispensed without a doctor's prescription.

# **XYLOVIT 0.1%**

## **Nasal drops/dosing spray-adults**

# **XYLOVIT 0.05%**

## **Nasal drops/dosing spray-children**

**Composition:** Xylovit 0.1%: Xylometazoline HCl 0.1%  
Xylovit 0.05%: Xylometazoline HCl 0.05%

For the list of inactive ingredients of the medicine, please see section 6 – "Additional information"

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine.

This medicine is dispensed without a doctor's prescription. The medicine is intended for adults, children and adolescents. It must be used correctly. Consult a pharmacist if you need additional information. Contact your doctor if disease symptoms worsen or do not improve.

### **1. What is the medicine intended for?**

**The medicine constricts the nasal blood vessels, thus reducing nasal congestion.**

**Indication:** For rapid relief of nasal congestion lasting up to 10 hours.

**Therapeutic group:** Contains xylometazoline hydrochloride belonging to the class of sympathomimetic agents.

### **2. Before using this medicine**

**Do not use the medicine if:**

- You have a known sensitivity to any of the medicine ingredients or similar preparations intended for the same purpose.
- You have undergone transsphenoidal hypophysectomy or nasopharyngeal operations.

**Special warnings related to the use of this medicine:**

- Do not use this medicine without consulting a doctor before starting treatment:** if you are pregnant or breastfeeding or if you suffer or have previously suffered from impaired function of the heart or blood vessels (arteriosclerosis), eyes (such as glaucoma), from impaired function of the liver, kidneys/urinary system, or from hyperthyroidism, hypertension or diabetes.
- Prolonged or excessive use** may result in worsening of congestion and injury of the nasal mucosa! Do not use this medicine frequently or for a prolonged period of time, without consulting your doctor. Do not use Xylovit for more than 3 days consecutively, unless prescribed by your doctor.
- If you are sensitive to any food or medicine, inform your doctor before taking the medicine.
- Drug interactions:** If you are taking other medicines, or have recently completed treatment with another medicine, notify your attending doctor to avoid the risks or inefficacy resulting from drug interactions, especially regarding anti-depressants such as monoamine oxidase inhibitors (MAOI), tricyclic and tetracyclic anti-depressants (simultaneous use may intensify the systemic effect of xylometazoline), and anti-hypertensive medicines such as methyl dopa or thyroxine.

**Important information about some of the ingredients of the medicine:**

Contains Benzalkonium Chloride 0.01% as a preservative.

### **3. How should this medicine be used?**

**Attention:** Do not swallow this medicine! It is intended for external use only.

**The standard dose (in the absence of other instructions provided by the doctor):**

**Adults and children above the age of 12 years – use Xylovit 0.1%:**

Drops: 2–3 drops every 8–10 hours.

Metered-dose spray: spray (by squeezing the bottle) once or twice every 8–10 hours.

**Children aged 2-12 years – use Xylovit 0.05%:**

Drops: 2–3 drops every 8–10 hours.

Metered-dose spray: spray (by squeezing the bottle) once every 8–10 hours.

This medicine is not usually intended for children and infants below the age of 2 years, unless administered according to a doctor's recommendation and under his supervision.

**Do not exceed the recommended dose.**

**If you forget to take the medicine** at the scheduled time, take a dose as soon as you remember, but never take two doses at the same time.

**How can you help ensure the success of the treatment?**

**Nasal drops:** a. How to use the drops: Blow your nose gently. Tilt your head backwards or lie down on a bed. Put the drops into each nostril and continue tilting your head backwards for a few minutes to allow the medicine to spread throughout the nasal cavity.

b. Rinse the dropper well with warm water and dry it with a clean paper towel. Take care not to let any water enter the bottle. Close the bottle tightly after use. c. To avoid cross-contamination, do not let anyone else use the same bottle.

**Nasal spray:** a. Blow your nose gently. With your head upright, spray the medicine into each nostril (while blocking the other nostril with a finger), as follows: breathe in short inhalations while squeezing the bottle with rapid, strong pressure. The number of times you squeeze the bottle will depend on the recommended dose. b. Wait 3-5 minutes. c. Gently blow your nose again, and repeat the procedure if necessary. d. Rinse the nozzle of the spray bottle with warm water, while taking care not to let any water enter the bottle. Dry with a clean paper towel and close tightly. e. To avoid cross-contamination, do not let anyone else use the same bottle. Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear reading glasses if you need them.

### **4. Side effects:**

Like any medicine, the use of Xylovit may cause side effects in some users. Do not be alarmed when reading the list of side effects – you may not suffer from any of them.

**The following side effects may occur:** a sensation of burning in the nose and throat, nose dryness, nausea, sneezing or tingling in the nose. These side effects usually resolve within a short time following the period of adaptation to the medicine. If they persist or bother you, consult your doctor.

**Side effects requiring special attention:** In case of recurrent nasal congestion or effects indicating possible systemic absorption (in the body), such as: headache, visual disturbances, sleep disturbances and stronger- or faster-than-usual heartbeats. Effects that may indicate an allergic reaction: difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, severe skin itching accompanied by a red rash or skin swellings: **stop the treatment and contact your doctor immediately!**

**Side effects and drug interactions in children and infants:** The parents must inform the attending doctor of any side effect and any other medicine administered to the child! See special side effects and drug interactions detailed above.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general condition, consult your doctor immediately.

### **5. How should this medicine be stored?**

• Store in a dark place at a temperature below 25°C.

• **Do not use the medicine after the expiry date** that appears on the package. The expiry date refers to the last day of that month. **Even if stored according to the recommended packaging/storage conditions**, medicines may be kept for a limited period only. In case of any doubt, consult the pharmacist who supplied the medicine to you. The medicine may be used for up to 6 months after the bottle is first opened, but no later than the expiry date indicated on the package.

• The medicine is a clear colorless solution.

• Store in the original package. Do not store different medicines in the same package.

• **Avoid poisoning!** This medicine and any other medicine must be stored in a safe place, out of the reach of children and/or infants, to avoid poisoning.

• If you have taken an overdose or if a child has accidentally swallowed the medicine, go to a hospital emergency room immediately, bringing the medicine package with you.

• **Do not induce vomiting** unless explicitly instructed to do so by your doctor!

### **6. Additional Information**

In addition to the active ingredients, the medicine also contains the following inactive ingredients:

Sodium Chloride, Potassium Chloride, Benzalkonium Chloride, Disodium Edetate, Disodium Hydrogenphosphate, Potassium Dihydrogenphosphate, purified water.

**Manufacturer:** Vitamed Pharmaceutical Industries Ltd., POB 114 Binyamina, 3055002, Israel.

This leaflet was checked and approved by the Ministry of Health in April 2015.

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