

This leaflet was formatted in accordance with Ministry of Health guidelines and was reviewed and approved in January 2015 by the Ministry of Health.

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

This medicine is dispensed without a doctor's prescription

## Xylo-Pos<sup>®</sup>, Nasal Spray

Name and concentration of active ingredient:

Xylometazoline hydrochloride 0.1%

See Section 6 for a list of inactive ingredients.

**Read this entire leaflet carefully before you start taking this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine is not intended for children under 12 years old, who are more sensitive to its side effects, unless recommended and monitored by a doctor.

Use this medicine correctly. Consult your pharmacist if you need further information. Consult your doctor if your signs of illness (symptoms) get worse or do not improve after 3 days.

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

- Fast relief of nasal congestion for up to 10 hours.
- Xylo-Pos constricts the blood vessels in your nose which reduces congestion. This allows patients with a cold to breathe through their nose.

**Therapeutic group:** sympathomimetic.

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

**Do not use this medicine:**

- If you are sensitive (allergic) to the active ingredient (xylometazoline hydrochloride) or to any of the other ingredients that this medicine contains or to similar medicines used for the same purpose.
- In case of an inflammation of the mucous membranes in your nose.
- After removal of your pineal gland through your nose or after other surgical intervention that exposes the brain membranes.
- After trans-sphenoidal removal of the pituitary through your nose or after nose and throat surgery.
- If you have increased pressure in the eye, particularly narrow-angle glaucoma.
- Children under 12 years old.

### **Special warnings about using this medicine:**

- **Before starting treatment with Xylo-Pos tell your doctor if:**
  - You have serious cardio-vascular diseases (such as coronary heart disease) and high blood pressure.
  - You have an enlarged prostate gland.
  - You have high blood pressure, heart disease, metabolic disorders such as: an over active thyroid and diabetes.
  - You have a benign tumor in your adrenal gland (pheochromocytoma).
  - You have porphyria.
  - You have had surgery in your nose and throat.
  - You are sensitive to any food or medicine.
- Prolonged or excessive use may cause chronic swelling and may damage your nasal mucous membranes.
- Do not use this medicine too often or for longer than 3 days without consulting your doctor. Wait a few days before you use this medicine again.
- If you have a chronic cold, only use this medicine under medical supervision

because of the potential harm to the mucous membrane in your nose.

**If you are taking, or have recently taken, any other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- antidepressants (such as tricyclic antidepressants, monoamine oxidase inhibitors) or medicines for blood pressure. Using these medicines with Xylo-Pos may raise your blood pressure because of the effect of Xylo-Pos on cardio-vascular function.

### **Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding, consult a doctor or pharmacist before using medicines.

There is not enough information about the safety of using this medicine during pregnancy and breastfeeding, so consult your doctor who will weigh the benefits against the risk.

### 3. **How to use this medicine?**

- Check with your doctor or pharmacist if you are not sure.

**The recommended dose for adults and for children over 12 years old is:**

one squirt in each nostril up to 3 times a day. Do not spray more than 3 times in 24 hours in each nostril.

**Do not exceed the recommended dose.**

- Do not swallow.
- This medicine is for external use only.

How to use this medicine - general instructions:

Before each use, take the cap off.

Blow your nose gently.

Press the pump mechanism several times until the solution is released (usually once or twice). The system is ready to use now.

Hold your head straight, insert the spray nozzle into your nostril and press once while gently breathing in. Spray once in each nostril up to 3 times a day, as needed.

Rinse the spray nozzle in warm water but make sure that no water gets into the bottle. Wipe with a clean paper towel and close firmly.

To prevent spreading the infection, do not use the same bottle for more than one person.

**If you have accidentally taken an overdose,** or if a child has accidentally swallowed some medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you. Signs of overdose can be confusing: periods of nervous system and cardio-vascular system arousal may turn into periods of depressed central nervous and cardio-vascular systems. Signs of arousal of the central nervous system: anxiety, hallucinations, and spasms. Signs of depression of the central nervous system: reduced body temperature, tiredness, sleepiness, and coma. The following symptoms may also occur: contraction or dilation of the pupils, fever, sweating, paleness, bluish skin caused by reduced level of oxygen in the blood, palpitations, cardiac arrest, lung edema, respiratory depression and respiratory arrest, nausea and vomiting, increased or reduced blood pressure, irregular heart rhythm, fast heart rhythm, slow heart rhythm.

**If you forget to take this medicine** at the scheduled time, continue taking it at the usual times. Never take two doses together!

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

If you have any further questions about using this medicine, consult your doctor or the pharmacist.

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

Like all medicines, using Xylo-Pos may cause side effects in some people. Do not be

alarmed by this list of side effects. You may not experience any of them.

Stop using the medicine and consult your doctor immediately if you experience any of the following side effects, which may be a sign of an allergic reaction:

- difficulty breathing or swallowing.
- Swelling of the face, lips, tongue, or throat.
- Severe itch together with a red rash or bumps on your skin.

**Common side effects**

- Stinging or dryness of the mucous membrane in your nose, sneezing.

**Uncommon side effects:**

- Hypersensitivity reactions (a condition that comes with itching, swelling of the skin and mucous membranes).
- Increase in swelling of the mucous membrane after the medicine's effect wears off, nosebleed.

**Rare side effects:**

- Palpitations, increased activity of the heart (tachycardia), increased blood pressure.

**Very rare side effects:**

- Restlessness, insomnia, tiredness (sleepiness, falling asleep), headache, hallucinations (mainly in children).
- Heart rhythm disorders.
- Spasms (mainly in children).

If you experience any side-effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

### 5. **How to store this medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this medicine after the expiry date stated on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine for longer than 12 weeks after opening.
- Do not throw away medicines into the wastewater or household waste. Ask your pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

### 6. **Additional information:**

**In addition to the active ingredient, this medicine also contains:**

sorbitol, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, disodium edetate, water for injections.

No preservative.

**What the medicine looks like and what are the contents of the package:**

A 15 ml plastic bottle of clear, colorless solution.

**Registration holder name and address:** Kivema Ltd. 33 Hahoresht St. Kfar Shemaryahu 4691000

**Manufacturer name and address:** URSAPHARM, Saarbrücken, Germany.

**Registration number of the medicine in the Ministry of Health National Drug Registry: 139-83-31417-00.**