

Dear patient!

Please read the following leaflet carefully, because it contains important information about what you should be aware of when using this medicine. If you have further questions, please contact your physician or pharmacist.

Product information

Xylometazoline hydrochloride 0.1%

Xylo-POS

Nasal spray, solution

Active ingredient: Xylometazoline hydrochloride

Composition:

1 spray of 0.14 ml contains:

- Medically active ingredient:
Xylometazoline hydrochloride 0.14 mg
- Other ingredients:
Disodium edetate, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sorbitol, purified water.

Xylo-POS does not contain any preservatives.

Administration form and contents:

15 ml nasal spray, solution

Mode of action:

Rhinologic agent, alpha-sympathomimetic

Xylometazoline has vasoconstrictive properties and thus effects decongestion of the nasal mucosa.

Therapeutic indications:

For temporary relief of nasal congestion in case of cold, vasomotor rhinitis or allergic rhinitis. To aid drainage of secretions in affections of the paranasal sinuses or in middle-ear catarrhs accompanied by cold.

Xylo-POS is intended for use by adults and children above 6 years.

Contraindications:

When should you not use Xylo-POS?

Xylo-POS should not be used if you are hypersensitive (allergic) to any of its ingredients, in cases of dry inflammation of the nasal mucosa (rhinitis sicca) or in children under the age of 6.

When should you use Xylo-POS only after consulting your doctor?

The following describes when you should use Xylo-POS only under certain conditions and with particular caution. Please ask your doctor. This also holds if this previously applied to you.

This preparation should be used only after careful consideration of the risks and benefits in:

- if you take mono-amino oxidase inhibitors (MAO inhibitors) or other drugs which potentially increase the blood pressure
- elevated intraocular pressure, particularly narrow-angle glaucoma
- severe cardiovascular diseases (e.g. coronary heart disease) and high blood pressure (hypertension)

- phaeochromocytoma
- metabolic disorders (e.g. hyperthyroidism, diabetes)

Pregnancy and breast-feeding:

Xylo-POS should not be used during pregnancy, since only insufficient investigations involving unborn children are available. Use when breast-feeding should be avoided, since it is not known whether the active ingredient is passed on in the breast milk.

What should be observed for children?

Long-term use and overdose should be avoided, particularly in children. Use at high doses should only be carried out under medical supervision.

Precautions for use and warning notes

Permanent use of decongestive nasal drugs can cause chronic swelling and finally decrease the nasal mucosa.

Patients suffering from glaucoma, in particular narrow-angle glaucoma, should ask their doctor before using cold remedies containing xylometazoline.

What should you remember while driving, working with machines or working in unsafe environments?

Following long-term use or high doses of Xylo-POS, effects on cardiac or circulator function or the nervous system cannot be excluded. In these cases, the ability to drive or operate machinery can be impaired. Please note especially that alcohol can affect your ability to drive even further!

Interactions with other drugs

What other drugs influence the effect of Xylo-POS?

If you use Xylo-POS at the same time as certain mood-lifters (MAO inhibitors of the tranylcypromine type or tricyclic antidepressants), the blood pressure can be increased due to effects on the cardiovascular functions.

Please observe that this also applies to drugs you have used recently.

Posology and method of administration

The following instructions apply unless your doctor has prescribed Xylo-POS differently for you.

Please observe the dosage instructions, since Xylo-POS may not work properly otherwise!

The recommended dose and duration of treatment must not be exceeded.

How much Xylo-POS should you use, and how often should you use it?

Unless prescribed otherwise, adults and school children apply one spray of Xylo-POS into each nostril up to three times a day, as necessary. The dose depends on the individual sensitivity and the clinical effect.

How long should you use Xylo-POS?

Xylo-POS should not be used longer than 5 days, except on medical advice.

You should wait for several days before you repeat the administration.

Generally ask your doctor how long a child should be treated.



If you suffer from chronic cold you should use the drug only under medical observation because of the risk of decrease of the nasal mucosa.

Overdose and other administration errors

What should you do if you have applied more of Xylo-POS than you should (intentional or accidental overdose)?

In case of overdose or accidental swallowing of Xylo-POS, the following effects can occur:

Enlargement of the pupils (mydriasis), sickness, bluish skin discolouration of the lips (cyanosis), fever, convulsions, cardiovascular problems (tachycardia, cardiac arrhythmia, ventricular standstill, hypertension), respiratory problems (pulmonary oedema, respiratory difficulties), psychogenic disturbances.

Sleepiness, lowering of the core body temperature, decrease of the heart rate, shock-like drop in blood pressure, respiratory arrest and coma can also occur.

Therapeutic actions include the administration of medicinal charcoal, gastric lavage or the administration of oxygen. Hypertension, fever and cramps may also require treatment.

What should you know if you forget to take Xylo-POS?

Do not use a double dose to make up for a forgotten dose. Instead, just continue the application according to the dosage instruction.

Side effects

What side effects can occur when you use Xylo-POS?

The evaluation of side effects is usually based on the following frequency rates:

very common: more than 1 in 10 patients
common: less than 1 in 10, but more than 1 of 100 patients
uncommon: less than 1 in 100, but more than 1 in 1,000 patients
rare: less than 1 in 1,000, but more than 1 in 10,000 patients
very rare: 1 case or less in 10,000 patients, including isolated cases

Respiratory tracts:

Xylo-POS can cause transient mild irritation (burning or dryness of the nasal mucosa), particularly in sensitive patients.

After subsiding of the effect, an increased swelling of the mucosa is commonly experienced (reactive hyperaemia).

Longer or frequent use and higher doses of Xylo-POS can cause irritation (burning or dryness of the mucosal tissue) and increased swelling of the mucosa, which is worsened by the increased use of medication (rhinitis medicamentosa). This effect can occur even after only five days of treatment, and can cause permanent mucosal damage with crustation (rhinitis sicca) in the event of continued use.

Nervous system:

Headache, insomnia or tiredness occur rarely.

Cardiovascular system:

Side effects involving the heart and the circulation, such as palpitations, tachycardia and increase in blood pressure, are uncommon.

Warning: If irritation persists or increases, discontinue use and consult physician.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Incompatibilities

None known.

Notes and instructions on storing the medication

Shelf life as packaged for sale: 3 years.

This medicinal product should not be used after the expiry date.

Shelf life after first opening of the bottle:

Do not use longer than 12 weeks after first opening.

Special precautions for storage:

Keep medicines out of the reach and sight of children. Store in a cool and dry place.

Nature and contents of the container:

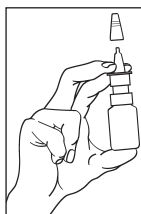
Xylo-POS is a clear, colourless solution, filled in a plastic bottle with dosing pump. A pre-package contains one bottle with 10 ml of solution.

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Handling

Remove the protective cap before use.



Press the pump mechanism until the solution is emitted (usually once or twice). The system is now ready for use for any further application.

Insert the spray opening in a nostril and pump once, breathing in lightly at the same time.

For hygienic reasons wipe off the nose adapter after each application and close it with the protective cap.

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