

Xylo-COMOD® Nasal spray

Dear Patient,

Please read this leaflet carefully because it contains important information for you. If you have further questions, please ask your physician or your pharmacist.

Xylo-COMOD® Nasal spray

Active ingredient: Xylometazoline hydrochloride

Composition:

1 ml of the solution contains:

- Active Ingredient:

Xylometazoline hydrochloride 1.00mg

- Other Ingredients:

Sodium edetate, sodium dihydrogen phosphate dihydrate; disodium phosphate dodecahydrate, sorbitol and purified water.

Pharmaceutical form and pharmaco-therapeutic group:

15 ml decongestive nasal spray.

Therapeutic Indications:

For the symptomatic relief of nasal congestion, perennial and allergic rhinitis (including hay-fever) and sinusitis.

Contraindications:

Xylo-COMOD® should not be used in cases of hypersensitivity against one of the ingredients, rhinitis sicca (inflammation of the nasal mucosa without mucus production) and vasomotor rhinitis. Children under the age of 6 years should not use Xylo-COMOD®.

Xylo-COMOD® normally should not be used in cases of glaucoma, severe cardiovascular disease (ischaemic heart disease, hypertension) and metabolic disorders (hyperthyroidism, diabetes mellitus). Care is also required in co-modification with monoamineoxidase inhibitors or other potential hypertensive drugs.

Precautions for Usage:

In the course of pregnancy and during lactation please contact your physician.

Special Warnings:

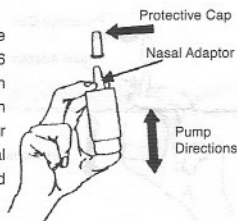
None.

Interactions:

In the case of application at the same time with other potential hypertensive drugs like monoamineoxidase inhibitors or tricyclic antidepressants an increase in blood pressure can not be excluded.

Instructions for proper usage:

If not otherwise prescribed the dose for adults and children of 6 years and above is 1 puff in each nostril 3 times daily. The duration of treatment should not be longer than 5 to 7 days. After an interval of some days a renewed application is possible.



Before first use of Xylo-COMOD® take off the protective cap and activate the spray with head upright until the first aerosol comes out. Now the bottle is ready for further applications. Insert the tube into each nostril and apply the nose spray while inhaling (sniffing) through the nose. After use close the bottle carefully. For further applications the bottle is ready for use.

Each Xylo-COMOD® pack should only be used by one person to prevent any cross-infection.

Side-effects:

A transient irritation like a burning sensation in the nose and throat or dryness of the nasal mucosa may occur, especially in sensitive patients. In rare cases, a reactive hyperaemia may occur with chronic use or when the drug is stopped. Headache, insomnia or tiredness are isolated phenomena. Heart consciousness, increase of blood pressure or pulse rate are very rare.

If you notice any side-effect which is not mentioned in this product information please inform your physician or pharmacist.

Storage Instructions:

Xylo-COMOD® should be stored at room temperature (25 °C).

Note:

Xylo-COMOD® can be used up to 12 weeks after the bottle has been opened. The drug should not be used beyond the expiration date (imprinted on the packaging carton).

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Date on which the package leaflet was last revised:

December 2000

Store this drug out of the reach of children!

THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription, without consulting your Doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.