

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Linex® for Kids

Metered nasal spray for children

Name and concentration of active ingredient

Xylometazoline hydrochloride 0.5 mg/ml (0.05%)

For inactive ingredients and allergens in the medicine, see section 6 - 'Additional information'.

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

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if the symptoms of illness get worse or do not improve after 3 days.

This medicine is not intended for children under 2 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended for rapid relief of nasal congestion for up to 10 hours in children aged 2-12 years.

Therapeutic group:

Sympathomimetics.

Medical activity:

Linex for Kids acts by constricting the nasal blood vessels, thus relieving congestion in the nose and adjacent pharyngeal areas and enabling rapid long-term relief of nasal congestion. As a result, Linex for Kids helps patients suffering from blocked nose to breathe more easily.

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 in this medicine - see section 6.
- You have had a transphenoidal hypophysectomy (through the nasal cavity) of the pituitary gland or oral or nasal surgery which exposed the external membrane of the central nervous system.
- You have chronic nasal inflammation (rhinitis) with very dry nasal passages.
- You have hypertension.
- You have diabetes.
- You have narrow angle glaucoma.
- You have an enlarged prostate gland.
- You have a rare tumor of the adrenal gland that produces an excess of adrenaline and noradrenaline (pheochromocytoma).
- You are taking medicines that inhibit the enzyme monoamine oxidase (MAO inhibitors) used for treatment of depression or have stopped taking them in the last 14 days.

Do not use Linex for Kids in children under 2 years of age.

Special warnings regarding use of this medicine

Before using this medicine, tell your doctor if:

- You have an overactive thyroid gland (hyperthyroidism)
- You have heart or circulatory disease (for example, long QT syndrome)
- Your child is taking medicines of the beta-blockers group (for treatment of heart rate problems, angina pectoris and hypertension)

In these cases, do not use Linex for Kids prior to consulting your doctor.

Additional warnings:

- Like other decongestants, Linex for Kids should be used with caution in patients strongly responding to adrenergic agents. People who are very sensitive to these agents may develop symptoms such as sleep disturbances, dizziness (vertigo), tremor, cardiac arrhythmias or increased blood pressure. Consult your doctor if these symptoms occur.
- Do not exceed the recommended dose.
- The medicine should be used by one patient only to avoid contamination.
- **Do not use Linex for Kids for more than 3 consecutive days.** If the symptoms do not resolve, consult your doctor. Prolonged or excessive use may cause the nasal congestion to return or get worse.

Children and adolescents

Do not use Linex for Kids in children under 2 years of age.

Interactions with other medicines

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

- Sympathomimetics (cutaneous and intestinal vasoconstrictors)
- Antidepressants, such as monoamine oxidase inhibitors (MAOIs), even if you have stopped taking them in the last 14 days, or tricyclic or tetracyclic antidepressants.

Pregnancy, breastfeeding, and fertility

The medicine is intended for use in children.

If you are pregnant or breastfeeding, think that you are pregnant or plan to become pregnant, consult your doctor or pharmacist before using Linex for Kids.

Pregnancy:

Use of Linex for Kids is not recommended during pregnancy.

Breastfeeding:

During the breastfeeding period, Linex for Kids should be used only according to a doctor's recommendation, since it is not known if the active ingredient is excreted in breast milk.

Fertility:

There is no information about the effect of Linex for Kids on fertility.

Driving and using machines

Linex for Kids has no effect on your ability to drive or use machines.

3. HOW TO USE THIS MEDICINE?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Children aged 2-12 years:

One spray in each nostril every 8-10 hours, as needed. Do not exceed 3 applications a day in each nostril.

This medicine is not intended for children and infants under 2 years of age, unless recommended and supervised by your doctor.

Do not exceed the recommended dose.

Treatment duration

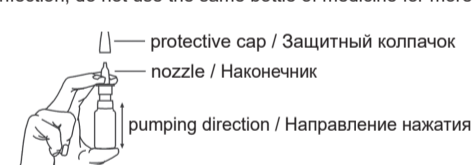
Do not use this medicine frequently or for more than 3 consecutive days without consulting a doctor. Prolonged or excessive use can make the congestion worse and damage the nasal mucosa. If your symptoms persist, consult your doctor.

Taking this medicine

Do not swallow; this medicine is intended for use in the nose only.

Instructions for use:

- There is no need to cut the bottle nozzle. The metered spray is ready for use.
- Before first use, remove the protective cap and prime the pump by pressing it several times (at least 4 times) until a uniform spray is released into the air. Be careful to avoid spraying in the eyes or in the mouth.
- Blow your child's nose gently before use.
- Hold the bottle upright with your thumb under its base and the nozzle between your two fingers (see figure below).
- Tilt your child's head forward slightly and insert the nozzle into the nostril.
- Press the pump once and at the same time, ask your child to inhale through the nose while pressing.
- Repeat the action in the other nostril.
- At the end of use, rinse the bottle tip with warm water. Take care not to get water in the bottle and wipe off with a clean tissue. Then close the bottle.
- To avoid spread of infection, do not use the same bottle of medicine for more than one person.



If you have accidentally taken a higher dose of Linex for Kids, you may experience severe dizziness, sweating, hypertension, significant decrease in body temperature, heart rate slowing, hyperventilation, respiratory depression, coma and seizures. Increased blood pressure may be followed by decreased blood pressure. Young children are more sensitive to overdose than adults.

Supportive treatment should be provided in case of a suspected overdose. The treatment includes medical supervision. In case of severe overdose with cardiac arrest, resuscitation attempts should be continued for at least 1 hour. In case of swallowing, notify a doctor immediately.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine at the scheduled time, you can take it as soon as you remember, within 1 hour of the original intake time. If you did not remember to take the medicine, skip the forgotten dose and take the next dose at the usual time. Do not take a double dose to make up for the forgotten dose.

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

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

4. SIDE EFFECTS

As with any medicine, using Linex for Kids spray may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using this medicine and **contact a doctor immediately** if you experience:

- allergic reactions, which may include difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin, with a red rash or raised bumps on the skin.

Common side effects - affect 1-10 in 100 users:

- Headaches • Insomnia • Weakness • Nasal mucosa dryness or hyperemia (irritation) • A burning sensation in the nose or throat • Local irritation • Nausea

Uncommon side effects - affect 1-10 in 1,000 users:

- Nosebleed

Very rare side effects - affect less than 1 in 10,000 users:

- Transient visual disturbances • Irregular or increased heart rate • Increased blood pressure • Allergic reactions such as skin rash, itching

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.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

• Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.

• Do not induce vomiting unless explicitly instructed to do so by a doctor.

• Do not use the medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.

• **Store in a cool dry place, below 25°C.**

• **This medicine can be used for up to one year after first opening, but not later than its expiry date.**

6. ADDITIONAL INFORMATION

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

Glycerol 85%, Sodium citrate 2 H₂O, Citric acid monohydrate, Water

What the medicine looks like and contents of the package:

A clear almost colorless solution supplied in a glass bottle with a plastic pump and cap.

Name and address of the license holder: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

Name and address of the manufacturer: Merckle GmbH, Blaubeuren, Germany.

This leaflet was revised in August 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 158.40.34687.00

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