

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

This medicine is dispensed without a doctor's prescription

Linex®

Metered nasal spray for adults

Name and concentration of active ingredient
Xylometazoline Hydrochloride 1 mg/ml (0.1%w/v)

Inactive ingredients: 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 your illness get worse or do not improve after 3 days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended for rapid relief of nasal congestion for up to 10 hours in adults and adolescents over 12 years of age.

Therapeutic group:
Sympathomimetics.

Linex helps to open up and clear the nasal passages by reducing the excessive nasal discharge and returning the swollen blood vessels to their original size.

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 (see section 6).
- You have had a transsphenoidal hypophysectomy (through the nasal cavity) of the pituitary gland or surgery which exposed the external membrane of the central nervous system.
- You have narrow angle glaucoma.
- You have chronic nasal inflammation with very dry nasal passages (atrophic rhinitis or rhinitis sicca).
- 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) or have stopped taking them in the last 14 days.

Do not use Linex in children under 12 years of age.

Special warnings regarding use of this medicine

Before using this medicine, tell your doctor if:

- You have hypertension
- You have heart or circulatory disease (for example, long QT syndrome)
- You have an overactive thyroid gland (hyperthyroidism)
- You have diabetes
- You are pregnant or breastfeeding
- You are taking tri and tetra-cyclic antidepressants

Like other decongestants, this medicine may cause sleep disturbances, dizziness and tremor in very sensitive patients. Consult your doctor if these symptoms are troublesome.

Do not use decongestants for more than 3 consecutive days. Prolonged or excessive use may cause the nasal congestion to return or get worse. If you are using Linex beyond the recommended treatment duration or dosage, consult your doctor or pharmacist.

Children and adolescents

Do not use Linex in children under 12 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:

Antidepressants of the monoamine oxidase inhibitors (MAOIs) group or other antidepressants.

Pregnancy, breastfeeding, and fertility

Use of Linex **is not recommended** if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, consult your doctor before using Linex.

Driving and using machines

Linex 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:

Adults and children over 12 years of age:

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

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.

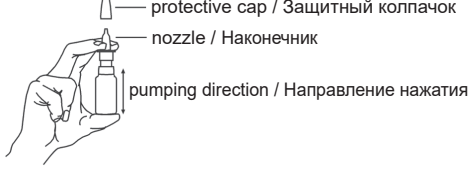
Taking this medicine

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.
- 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 nose gently.
- Hold the bottle upright with your thumb under its base and the nozzle between your two fingers (see figure below).
- Lean forward slightly and insert the bottle nozzle into the nostril.
- Press the pump once and inhale gently at the same time.
- Repeat the action in the other nostril.

Rinse the bottle tip with warm water. Take care not to get water in the bottle. Wipe off with a clean tissue and 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 an overdose

You may experience severe dizziness, sweating, low body temperature, headache, slow heart rate, hypertension, respiratory depression, coma and seizures. Hypertension may occur following a decrease in blood pressure. Young children are more sensitive to overdose than adults.

If you have accidentally taken an overdose, 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, do not take a double dose. Take the next dose at the usual time and consult your doctor.

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 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.
- Nasal mucosa dryness.
- Nasal discomfort.
- Nausea.
- Local irritation after using the spray.

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

- Nosebleed.

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

- Hypersensitivity reaction including skin rash, itching.
- Visual disturbances.
- Palpitations and increased heart rate.
- Apnea in young infants and newborns.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- A burning sensation in the nose and throat.

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.

Storage conditions

- 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 for injections.

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.

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Registration number of the medicine in the Ministry of Health's National Drug Registry: 158.41.34689.00

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