

**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

**Linex spray contains** Xylometazoline hydrochloride 1 mg/ml (0.1%)

## Linex® for Kids

### Metered nasal spray for children

#### Name and concentration of active ingredient

**Linex for Kids spray contains** Xylometazoline hydrochloride 0.5 mg/ml (0.05%)

**For a list of inactive ingredients, please 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 your signs of illness (symptoms) get worse or do not improve after 3 days.

**Linex** is only intended for adults and children over 12 years old.

**Linex for Kids** is intended for children of 2-12 years old. This medicine is not intended for children under 2 years old.

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

This medicine is intended for rapid relief of congestion in the nose for up to 10 hours.

#### **Therapeutic group:**

This medicine contains xylometazoline hydrochloride which is a sympathomimetic. This medicine 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 in this medicine - please 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 (rhinitis sicca) or (atrophic rhinitis).
- 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 monoamine oxidase inhibitors (MAOIs) or have stopped taking them in the last 14 days.
- Do not use **Linex** in children under 12 years old.
- Do not use **Linex for Kids** in children under 2 years old.

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

##### **Before using this medicine, tell your doctor if:**

- You have an overactive thyroid gland (hyperthyroidism)
- You have diabetes
- You have heart or circulatory disease (for example, long QT syndrome)
- You are pregnant or breastfeeding
- You have high blood pressure

Like other decongestants, this medicine may cause sleep disturbances, dizziness and tremor in people who are very sensitive to this. 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 congestion to return or get worse.**

#### **Children and adolescents**

Do not use **Linex** in children under 12 years old.

Do not use **Linex for Kids** in children under 2 years old.

#### **Drug interactions**

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

Antidepressants, especially monoamine oxidase inhibitors (MAOI).

#### **Pregnancy, breastfeeding, and fertility**

Use of **Linex** or **Linex for Kids** during pregnancy is not recommended.

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

#### **Driving and using machines**

**Linex** products have no effect on your ability to drive and 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:**

**Linex spray is intended for adults and children over 12 years old:**

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

**Linex for Kids spray is intended for children ages 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 usually not intended for children and infants under 2 years old unless advised 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.

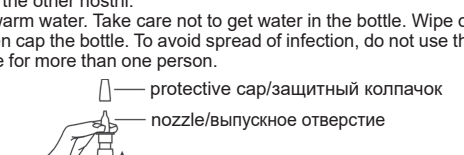
##### **Taking this medicine**

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 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 nozzle into a nostril.
- Press the pump once and inhale gently at the same time.
- Repeat the action for the other nostril.

Rinse the nozzle with warm water. Take care not to get water in the bottle. Wipe off with a clean tissue. Then cap 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, 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

**Like with all medicines, using Linex spray and 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
- Nasal mucosa dryness
- Nasal discomfort
- Nausea
- Local irritation after using the spray

##### **Very rare side effects - affect less than 1 in 10000 users:**

- Visual disturbances
- Hypersensitivity including skin rash, itching
- Palpitations and increased heart rate

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

- A burning sensation in the nose and throat

**Side effects and drug interactions in children and infants:** Parents should tell their doctor about any side effect and about all other medicines that their child is given!

**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 of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://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! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. 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 is stated 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 and no later than its expiry date.**

#### 6. Additional information

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

Glycerol 85%, Sodium citrate 2 H<sub>2</sub>O, Citric acid monohydrate, Water

##### **What the medicine looks like and contents of the pack:**

This medicine is a clear almost colorless solution supplied in a glass bottle with a pump and plastic cap.

**Registration holder's name and address:** Abic Marketing Ltd., P.O.B 8077, Netanya (Teva Group).

**Manufacturer's name and address:** Merkle GmbH, Blaubeuren 89143, Germany.

This leaflet was revised in March 2021 according to MOH guidelines.

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

**Linex Spray:** 158.41.34689

**Linex for Kids Spray:** 158.40.34687