

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

Otrivin Kids 0.05% w/v

Nasal Solution Drops

Metered Dose Nasal Solution Spray

Active ingredient

Xylometazoline Hydrochloride 0.05% w/v

Inactive ingredients and allergens in the preparation – see section 6 and section 2 under the heading “Important information about some of the ingredients of the medicine”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in section “How should you use the medicine?” in this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if symptoms of the ailment worsen or do not improve after 3 days.

1. What is the medicine intended for?

For rapid relief of nasal congestion for up to 10 hours in children aged 2-12 years.

Therapeutic class: sympathomimetic agents.

Therapeutic activity:

Xylometazoline constricts blood vessels, thus reducing swelling of the mucous membrane.

2. Before using the medicine

X Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients the medicine contains (see section 6).
- After a trans-sphenoidal resection (through the nasal cavity) of the pituitary gland or a surgery through the nose or mouth during which the outer meninges of the central nervous system were exposed.
- If you have narrow angle glaucoma.
- If you have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis).
- If your child is under 2 years of age.
- If you have an enlarged prostate gland.
- If you have a rare tumor in the adrenal gland that produces excess adrenaline and noradrenaline (pheochromocytoma).
- If you are taking medicines that inhibit the enzyme monoamine oxidase (MAO inhibitors) or if you have stopped taking them in the last 14 days.

! Special warnings regarding the use of the medicine

As with other decongestants, Otrivin Kids may cause sleeping problems, dizziness, tremor, heart rate disturbances or an increase in blood pressure in highly sensitive patients.

Before treatment with Otrivin Kids, inform the doctor if:

- You or your child suffers from hypertension.
- You or your child suffers from cardiovascular diseases.
- You or your child suffers from heart problems (such as QT interval prolongation syndrome).
- You or your child suffers from an overactive thyroid gland.
- You or your child suffers from diabetes.
- You or your child is taking antidepressants such as: tricyclic and tetracyclic antidepressants.

! Children and adolescents

Do not use Otrivin Kids in children under the age of two years. In children aged 2-12 years, Otrivin Kids should be used under adult supervision.

! Duration of treatment

As with other decongestants, do not use Otrivin kids for more than 3 consecutive days. If symptoms persist, consult with a doctor. Prolonged or excessive use may cause chronic swelling (rhinitis medicamentosa) and/or degeneration of nasal mucosal tissue.

! Drug interactions:

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

- Antidepressants such as monoamine oxidase inhibitors (MAOIs) or medicines of the tricyclic or tetracyclic group. Concomitant use of these medicines with Otrivin Kids can lead to an increase in blood pressure due to the effect on the functioning of the heart and on the blood system.

! Pregnancy, breastfeeding and fertility

The product is intended for use in children.

If you are pregnant or breastfeeding, think that you might be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using Otrivin Kids.

Pregnancy

The use of Otrivin Kids is not recommended during pregnancy.

Breastfeeding

Do not use Otrivin Kids while breastfeeding, as it is not known whether the active ingredient is excreted into breast milk.

Fertility

No information is available regarding the effect of Otrivin Kids on fertility. No animal studies are available.

! Driving and operating machinery:

Otrivin Kids is intended for use in children. Otrivin Kids has no effect on the ability to operate machinery.

! Important information about some of the ingredients of the medicine

The formula contains benzalkonium chloride at a concentration equivalent to 0.1 mg/ml.

- Metered dose spray: 0.007 mg in one spray.
- Drops: 0.0025 mg in one drop.

Benzalkonium chloride may cause irritation or swelling of the nasal cavity, especially with prolonged use.

3. How should you use the medicine?

Otrivin Kids should only be used under adult supervision, in children aged 2-12 years.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

For children aged 2-12: 2-3 drops or one spray in each nostril, every 8-10 hours.

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

Do not exceed the recommended dose.

Duration of treatment

Do not use Otrivin Kids for more than 3 consecutive days.

Method of use:

For nasal use

Nasal drops:

1. Blow the child's nose before using Otrivin Kids.
2. Before use, prepare the dropper to obtain a uniform distribution of the dosage.
3. Tilt your child's head slightly back, in a way that feels comfortable for him.
4. Without touching your child's nose with the dropper, very carefully drip Otrivin Kids into your child's nostril. Keep your child's head tilted back for a few minutes to allow the drops to be absorbed in the nose. (See Figure A)



Figure A

5. If the drop does not get into your child's nostril, use another drop.
6. Do not drip another drop if some of the drop gets into your child's nostril.
7. Repeat these steps in the other nostril.
8. Clean the dropper before replacing it back into the bottle at the end of use.
9. To prevent the spread of infection, this package is intended to be used by one person only.

Metered dose nasal spray:

The spray package should be held with the nozzle facing up so that the solution is released optimally.

Be very careful not to spray into and around the eyes.

Remove the protective cap.

Do not cut the nozzle (see Figure B). The metered dose spray is ready for use.



Figure B

Before the first use, prime the pump by pumping 4 times. Once primed, the pump will usually remain charged throughout the periods of daily treatment. If the spray is not ejected following full actuation of the pump, or if the medicine has not been used for longer than 7 days, the pump will need to be reprimed. Press the pump twice as initially performed.

Be careful not to spray into the eyes.

1. Blow the child's nose before use.
2. Hold the bottle in an upright position with the thumb under its base and the nozzle between your two fingers. (See Figure C)



Figure C

3. Tilt the child's head slightly forward and insert the nozzle into the nostril.
4. Press the pump and ask the child to inhale gently through the nose while pressing. (See Figure D)



Figure D

5. Repeat these steps in the other nostril.
6. Immediately after use, clean and dry the nozzle before replacing the protective cap.

If possible, use the last dose of the day as close as possible to bedtime.

For hygienic reasons and to prevent the spread of infection, this package is intended to be used by one person only.

If you have accidentally taken a higher dosage of Otrivin Kids

The clinical picture following an overdose can be confusing, as stages of nervous system and cardiovascular system stimulation can turn into stages of depression. Symptoms of nervous system stimulation include anxiety, restlessness, hallucinations and convulsions. Symptoms of nervous system depression include decreased body temperature, fatigue, drowsiness and coma.

The following symptoms may also occur: constriction of the pupils (miosis), dilation of the pupils (mydriasis), excessive sweating, fever, pallor, appearance of bluish color in the skin due to a decrease in the amount of oxygen in the blood (cyanosis), nausea, irregular heart rhythm, heart rate that is too fast or too slow, palpitations, cardiac arrest, an increase or decrease in blood pressure, pulmonary edema, breathing suppression, sleep apnea.

Especially in children, an overdose often leads to effects on the nervous system such as convulsions and coma, low heart rate, sleep apnea and an increase in blood pressure that may be followed by a decrease in blood pressure.

If you have taken an overdose or if a child has accidentally swallowed this medicine, immediately go to a doctor or to a hospital emergency room and take the package of the medicine with you, since hospital supervision and treatment will be required.

If you have forgotten to take the medicine, do not take a double dose in order to compensate for the forgotten dose.

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

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Otrivin Kids may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Common side effects – effects that occur in 1-10 users out of 100:

- Headaches
- Dryness of the nasal mucosa
- Nasal discomfort
- Sneezing
- Nausea
- A burning sensation in the nose or throat

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Nosebleed
- An increased sensation of nasal congestion after the effect of the medicine wears off

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Palpitations
- Accelerated heart rate
- Increased blood pressure

Very rare side effects – effects that occur in less than one user out of 10,000:

- Hypersensitivity (swelling of the skin or mucosal membranes, skin rash, itch)

- Restlessness
- Insomnia
- Tiredness (drowsiness, sleepiness)
- Hallucinations (especially in children)
- Transient visual disturbances
- Irregular or increased heart rate
- Sleep apnea in young infants and newborns
- Convulsions (especially in children)

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store at a temperature lower than 30°C, in the original package.

6. Additional information

- **In addition to the active ingredient the medicine also contains:**
Otrivin Kids Drops and Metered Dose Spray:
Sorbitol 70% (non crystallizing), Methylhydroxypropylcellulose 4000 mPa.s, Sodium Dihydrogen Phosphate dihydrate, Sodium Chloride, Disodium phosphate dodecahydrate, Disodium edetate, Benzalkonium Chloride, Purified Water.
- **What does the medicine look like and what are the contents of the package?**
Otrivin Kids is a clear solution that comes in several forms of administration:
Nasal drops: a clear solution in a 10 ml bottle with a built-in dropper cap.
Metered dose nasal spray: a clear solution in a 10 ml bottle with an integrated pump providing a uniform dose in each spray.
- **Marketing authorization holder and address:** Haleon CH Israel Ltd., P.O. box 3256, Petach Tikva.
- **Name and address of the manufacturer:** Haleon SARL, Route de l’Etraz 1260, Nyon, Switzerland.

Revised in June 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health:

108-21-23658-00

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