

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

1986

This medicine is dispensed without a doctor's prescription

Otrivin

Nasal Solution Drops 0.1% w/v

Otrivin

Nasal Solution Metered Dose

Spray 0.1% w/v

Otrivin

Nasal Solution Spray 0.1% w/v

Active ingredient and its concentration

Xylometazoline Hydrochloride 0.1% w/v

Inactive ingredients and allergens in the preparation – please see section 6 and section 2 (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 any other questions, refer to the doctor or the pharmacist. Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 3 days.

1. What is the medicine intended for?

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

Therapeutic class:

Otrivin contains xylometazoline hydrochloride, which belongs to the class of sympathomimetic agents. Otrivin helps open and clear the nasal passages by reducing the formation of excess nasal secretions and returning the swollen blood vessels to their original size.

2. Before using the medicine

Do not use the preparation if:

- You are sensitive (allergic) to the active ingredient (xylometazoline hydrochloride) or to any one of the other ingredients the medicine contains – please see section 6.
- You are after a trans-sphenoidal resection (through the nasal cavity) of the pituitary gland or an operation during which the outer meninges of the central nervous system were exposed.
- 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 in the adrenal gland that produces excess adrenaline and noradrenaline (pheochromocytoma).
- You are taking medicines that inhibit the enzyme monoamine oxidase (MAO inhibitors) or if you have stopped taking them in the last 14 days.

Do not use the preparation in children under the age of 12 years.

Special warnings regarding the use of the medicine:

Before using Otrivin tell the doctor if:

- You have an overactive thyroid gland (hyperthyroidism)
- You have diabetes
- You have heart or vascular disease (e.g.: long QT syndrome)
- You are pregnant or breastfeeding
- You have hypertension.

As with other decongestants, Otrivin may cause sleep disturbances, dizziness and tremor in people who are very sensitive to it. Consult the doctor if these symptoms bother you.

Do not take decongestants for more than 3 consecutive days. Prolonged or excessive use may cause recurrence or worsening of the congestion.

Children and adolescents:

Do not use the medicine in children under the age of 12 years.

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:

Medicines for treatment of depression, particularly from the group of monoamine oxidase inhibitors (MAOI).

Pregnancy, breastfeeding and fertility:

Using Otrivin is not recommended if you are pregnant or breastfeeding. Consult the doctor before using Otrivin.

Driving and operating machinery:

Otrivin has no effect on the ability to drive or 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: 0.014 mg in one spray.

Drops: 0.0025 mg in one drop.

Spray: it is not possible to determine exactly because the quantity depends on the way the user squeezes the bottle.

Benzalkonium chloride may cause irritation or swelling in the nose, especially if used for a long time.

3. How should you use the medicine?

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

The generally accepted dosage is:

Otrivin Drops:

For adolescents above 12 years of age and for adults: 2-3 drops in each nostril, every 8-10 hours, as necessary. Do not exceed 3 applications per day into each nostril.

Otrivin Spray:

For adolescents above 12 years of age and for adults: one spray in each nostril, every 8-10 hours, as necessary. Do not exceed 3 applications per day into each nostril.

Otrivin Metered Dose Spray:

For adolescents above 12 years of age and for adults: one spray in each nostril 3 times per day, as necessary. Do not exceed 3 applications per day into each nostril.

Do not exceed the recommended dose.

Duration of treatment:

Do not use this medicine frequently or for more than 3 consecutive days without consulting the doctor. Prolonged or excessive use may cause worsening of the congestion and damage the nasal mucosa. If the symptoms persist, consult the doctor.

Method of administration:

Do not swallow, this medicine is intended to be used in the nose only.

Method of use:

Otrivin Drops:

1. Blow your nose.
2. Tilt your head backwards (see Figure A).
3. Apply 2-3 drops into each nostril and keep your head back for a short time.
4. Clean and dry the dropper before replacing it in the bottle.

To prevent the spread of infection, this pack is intended to be used by one person only.

Otrivin Spray:

1. Blow your nose.
2. Lean slightly forward and insert the nozzle into the nostril (see Figure B).
3. Squeeze the bottle once and inhale gently at the same time.
4. Remove the nozzle from the nostril before releasing the pressure from the bottle.
5. Repeat these steps in the other nostril.

To prevent the spread of infection, this pack is intended to be used by one person only.

Otrivin Metered Dose Spray:

1. Do not cut the nozzle (see Figure C). The Metered Dose Spray is ready for use.
2. Blow your nose.
3. Remove the protective cap.

Before the first use, prime the pump by pumping 4 times. Once primed, the pump will normally remain charged throughout the daily treatment period. 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 4 times as initially performed. Be very careful not to spray into your eyes or mouth.

4. Hold the bottle in an upright position with the thumb under its base and the nozzle between your two fingers.
5. Bend your head slightly forward and insert the nozzle into the nostril.
6. Press the pump while inhaling through the nose.
7. Repeat these steps in the other nostril.
8. Immediately after use, clean and dry the nozzle before replacing the protective cap.

To prevent the spread of infection, this pack is intended to be used by one person only.

Figure A



Figure B



Figure C



Do not exceed the recommended dose.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult a doctor.

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 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.

Stop using the 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 skin itch accompanied by a red rash or skin bumps.

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

- Headaches
- Dryness of the nasal mucosa
- Nasal discomfort
- Nausea
- Local irritation after using the spray.

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

- Nosebleed.

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

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

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- A burning sensation in the nose and throat.

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 your 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 below 30°C, in the original package.

6. Additional information

- **In addition to the active ingredient the medicine also contains:**
Otrivin Drops, Spray and Metered Dose Spray:

Sorbitol 70% (non crystallising), 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 Drops, Spray and Metered Dose Spray are clear solutions that come in several forms of administration:

Nasal Drops: a clear solution in a 10 ml bottle with a built-in dropper cap.

Nasal Spray: a clear solution in a 10 ml plastic squeeze bottle.

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:** GSK Consumer Healthcare Israel Ltd., P.O. Box 3256, Petah Tikva.
- **Name and address of the manufacturer:** GSK Consumer Healthcare SARL, Route de l'Etraz, 1260 Nyon, Switzerland.

Revised in January 2022 in accordance with the Ministry of Health guidelines.

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

Otrivin Drops, Spray and Metered Dose Spray: 115-43-22229-00

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