

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

This medicine is dispensed without a doctor's prescription

Otrivin Menthol 0.1% Intra-nasal solution

The active ingredient and its concentration:

Xylometazoline HCl 0.1%

Inactive ingredients and allergens in the preparation – please see section 6 and section 2 (Important information about some 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.

Therapeutic class: Otrivin Menthol contains xylometazoline hydrochloride, which belongs to the sympathomimetic agents group. It also contains menthol and eucalyptus.

2. Before using the medicine

X Do not use this preparation if:

- You are sensitive (allergic) to the active ingredient (xylometazoline hydrochloride) or to any of the other components the medicine contains (see section 6).
- You have narrow angle glaucoma.
- You have had a trans-sphenoidal resection of the pituitary or an operation during which the outer meninges of the central nervous system was exposed.

Special warnings regarding the use of the medicine:

Before treatment with Otrivin Menthol, inform the doctor if:

- You have high blood pressure.
- You have a heart disease or long QT syndrome.
- You have an overactive thyroid.
- You have diabetes.

As with other medicines for relief of nasal congestion, Otrivin Menthol may cause sleep disturbances, dizziness, tremor in highly sensitive patients. Consult with your doctor if these symptoms bother you.

Do not use this medicine frequently or for more than 3 consecutive days. If symptoms persist, consult with your doctor. Prolonged or excessive use may cause recurrence or worsening of nasal congestion.

- Otrivin Menthol is not intended to be used in the eyes or swallowed.
- Do not exceed the recommended dose, especially in children and the elderly.

Children and adolescents:

Otrivin Menthol is not intended for children and adolescents under the age of 12.

Drug-drug interactions:

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking antidepressants of the monoamine oxidase inhibitors group or the tricyclic or tetracyclic group.

Pregnancy, breastfeeding and fertility:

Pregnancy:

Do not use the medicine during pregnancy.

Breastfeeding:

If you are breastfeeding, consult with the doctor before using Otrivin Menthol.

Fertility:

Not enough information is available regarding the effects of the medicine on fertility. Since the medicine is absorbed into the body in small amounts, an effect on fertility is highly unlikely.

Important information about some ingredients of the medicine:

The medicine contains 0.014 mg of benzalkonium chloride in one puff, which is equivalent to a concentration of 0.1 mg per ml. Benzalkonium chloride may cause intranasal irritation or swelling, especially if the preparation is being used for long periods of 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:

For children above 12 years of age and adults:

One puff in each nostril, 3 times per day, as necessary. Do not exceed a dosage of 3 puffs in each nostril per day.

This medicine is not intended for children under 12 years of age.

Do not swallow. This medicine is intended for external use only.

Method of use:

1. Blow your nose gently.
2. Remove the protective cap.
Do not cut the nozzle (see figure 1). The metered-dose spray is ready for use.



Figure 1

Before the first application, prime the pump by pumping 4 times. Once primed, the pump will normally remain charged throughout the period of regular daily treatment. If the spray is not ejected following full actuation stroke or if the medicine has not been used for several days, the pump will need to be re-primed. Press the pump 4 times as initially performed. Be careful not to spray the medicine into the eyes or mouth.

3. Hold the bottle in an upright position, with your thumb under its base and the nozzle between two fingers.
4. Lean your head slightly forward and insert the nozzle into the nostril.
5. Spray while breathing and gently breathe in through your nose.
6. Repeat this procedure in the other nostril.
7. Clean and dry the nozzle before replacing the protective cap immediately after use.

In order to avoid spreading the infection, a single bottle of medicine should not be used by more than one person.

Do not exceed the recommended dose.

Duration of treatment

Do not use the medicine for more than **3 consecutive days**. If the symptoms persist, consult with the doctor.

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or the emergency room of a hospital immediately and take 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.

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 use of the medicine, consult the doctor or the pharmacist.

4. Possible side effects

As with any medicine, using Otrivin Menthol 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 refer to a doctor immediately if you feel any of the following side effects, which may indicate an allergic reaction:

- Difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe skin itch accompanied by a red rash or skin bumps.

Additional side effects:

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

Dryness or irritation in the nasal mucosa, nausea, headaches, local burning sensation.

Very rare side effects (occurring in less than one out of 10,000 users):

Allergic reactions (skin rash, itch), blurry vision, rapid or irregular heart rate.

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>

In addition, you can report to GSK Israel at il.safety@gsk.com

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 25°C.

6. Additional information

- In addition to the active ingredient, the medicine also contains: Sorbitol, Sodium Chloride, Disodium phosphate dodecahydrate, Castor Oil Polyoxyl hydrogenated (Cremophor RH 40), Sodium Dihydrogen Phosphate dihydrate, Disodium Edetate, Levomenthol (Menthol), Cineol (Eucaliptol), Benzalkonium Chloride, Purified water.

What does the medicine look like and what are the contents of the package:

Otrivin Menthol is a white solution with menthol and eucalyptus scent in a metered-dose spray bottle. The bottle contains 10 ml.

- **License holder and address:** GSK Consumer Healthcare Israel Ltd., P.O. Box 3256, Petah Tikva.
- **Name and address of the manufacturer:** GlaxoSmithKline Consumer Healthcare Switzerland AG, Risch, Switzerland.

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Registration number of the medicine in the national drug registry of the Ministry of Health: 1088929108

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