

Otrivin

Patient Information Leaflet (PIL)

Otrivin Menthol 0.1%

Metered Dose Spray

For Nasal Administration ONLY

Composition: Each ml contains 1 mg Xylometazoline Hydrochloride
Each metered dose Spray delivers 0.14 ml per actuation (0.14 mg of Xylometazoline Hydrochloride)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse.

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1. What Otrivin Menthol 0.1% is and what it is used for?

Otrivin Menthol 0.1% is used for various types of colds. It is designed to be applied in the nostrils, where it exerts a vasoconstricting effect thereby decongesting the mucosae of the nose and the throat.

This effect allows patients with colds to breathe more easily through the nose. Otrivin Menthol 0.1% facilitates the flow of secretions in inflammation of the sinuses. In otitis media, as an aid for decongesting the nasopharyngeal mucosa.

To facilitate rhinoscopy.

The action of Otrivin Menthol 0.1% is felt within a few minutes and lasts for several hours.

- * Otrivin Menthol 0.1% should not be used for longer than 1 week since prolonged use can lead to damage to mucosa (rhinitis medicamentosa).

2. What you need to know before you use Otrivin Menthol 0.1%?

a. Do not use Otrivin Menthol 0.1% if:

- You are allergic to xylometazoline or any other ingredients of this medicine.
- You have undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth).
- You have narrow angle glaucoma (increased pressure in eyes).
- You have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis).
- * Tell your doctor or pharmacist if any of the above apply because Otrivin Menthol 0.1% is not suitable for you in these circumstances.

b. Warnings and precautions

Talk to your doctor or pharmacist before using Otrivin Menthol 0.1% if:

- You have high blood pressure.
- You suffer from a heart disease. Patients with a long QT syndrome have an increased risk of severe ventricular arrhythmia when undergoing treatment with Xylometazoline.
- You have an overactive thyroid gland (hyperthyroidism).
- You suffer from diabetes.
- You have an enlarged prostate gland (prostatic hypertrophy).
- You have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma).
- You are being treated with some antidepressants known as monoamine oxidase inhibitors (MAOIs) or if you have used them within the previous 2 weeks.
- If any of the above apply, do not use Otrivin Menthol 0.1% before talking to your doctor or pharmacist.

- Like other products for the relief of blocked nose, Otrivin Menthol 0.1% may give rise to sleep disturbances, dizziness, tremor in very sensitive patients. Consult your doctor if such signs prove troublesome.

- Like other nasal decongestants, Otrivin Menthol 0.1% should not be used for more than 7 consecutive days. If symptoms persist, consult your doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen.

- Otrivin Menthol 0.1% is not intended for use in the eyes or mouth.
- Do not exceed the recommended dosage, especially in children and in the elderly.
- Otrivin Menthol 0.1% should be used for children below 12 years of age.

c. Taking Other medicines with Otrivin Menthol 0.1%:

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, you should not use Otrivin Menthol 0.1% if you are taking:
- * Certain medicines used for treatment of depression. These medicines are:
 - Monoamine oxidase inhibitors (MAOI); do NOT use Otrivin Menthol 0.1% if you are taking or have been taking MAOIs within the last 14 days.
 - Tri-cyclic and tetra-cyclic antidepressants.
 - * Potentially hypertensive medicines or medicines for Parkinson's disease (levodopa). If you use any of the above medicines, consult a doctor before using Otrivin Menthol 0.1%.

d. Pregnancy and breast-feeding

Otrivin Menthol 0.1% should not be used during pregnancy.

- The use of Otrivin Menthol 0.1% while breast-feeding should only take place on the instructions of a doctor.

- Fertility: There are no relevant data on the effect of Otrivin Menthol 0.1% on fertility, and controlled studies in animals are not available. Since systemic exposure to xylometazoline is very low, effects on fertility are highly unlikely.
- Ask your doctor or pharmacist for advice before taking any medicine.

e. Driving and using machines

- If used within the recommended dosing, there is no or negligible influence on the ability to drive and use machines.
- If used over a longer term or at higher doses, the potential for systemic activity with cardiovascular effects cannot be excluded.

3. How to use Otrivin Menthol 0.1%?

- * For Nasal administration ONLY.
- * Do not get Otrivin Menthol 0.1% in the mouth or eyes.
- * Do not exceed the recommended dose, especially in the elderly.
- * It is recommended to make the last application shortly before going to bed.
- * Otrivin Menthol 0.1% should not be used for longer than 1 week since prolonged use can lead to damage to mucosa (rhinitis medicamentosa).
- * Always use Otrivin Menthol 0.1% exactly as recommended below. You should check with your doctor or pharmacist if you are not sure.

Age	Dose
Otrivin Menthol 0.1% is only suitable for adults and adolescents aged 12 years and over.	1 puff in each nostril. Repeat the administration as needed; no more than 3 applications per day should be used. The last application of the day should preferably be made shortly before going to bed.

*Do not use for children under 12 years of age.

- **If you forget to use Otrivin Menthol 0.1%:**
 - Do not take a double dose to make up for a forgotten one.

- **Overdose:**
 - Excessive administration of topical xylometazoline hydrochloride or accidental ingestion may cause severe dizziness, perspiration, severely lowered body temperature, headache, bradycardia, hypertension, respiratory depression, coma and convulsions. Hypertension may be followed by hypotension. Small children are more sensitive to toxicity than adults.
 - Appropriate supportive measures should be initiated in all individuals suspected of an overdose, and urgent symptomatic treatment under medical supervision is indicated when warranted. This would include observation of the individual for several hours. In the event of a severe overdose with cardiac arrest, resuscitation should be continued for at least 1 hour.

• Instructions for using Otrivin Menthol 0.1% Metered Dose Nasal Spray:

1. Do not cut the nozzle. The metered dose spray is ready to prime before use.



2. Clear your nose.
 3. Remove protective cap.
 4. Before using for the first time, prime the pump by actuating 4 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be reprimed with 4 actuations. Be very careful not to spray in the eyes or mouth.
 5. Hold the bottle upright with thumb under base and nozzle between two fingers (Fig.1).
 6. Lean forward slightly and insert the nozzle into the nostril.
 7. Spray and breathe in gently through the nose at the same time (Fig.2).
 8. Repeat with the other nostril.
 9. Clean and dry the nozzle before replacing back the cap right after use.
 10. To avoid possible spread of infection, the spray should only be used by one person.
- * If you have any further questions on the use of this product, ask your doctor or pharmacist.



4. Possible Side Effects:

Like all medicines, Otrivin Menthol 0.1% can cause side effects, although not everybody gets them.

STOP using Otrivin Menthol 0.1% and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- Difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin, with a red rash or raised bumps.
- Irregular Heartbeat.

Common side effects (may affect up to 1 in 10 people):
Dryness or irritation of the nasal mucosa, rhinitis medicamentosa, nausea, headache, local burning sensation. May cause stomach upset and diarrhea.

Very rare side effects (may affect less than 1 in every 10,000 people):
Allergic reactions (skin rash, itching), blurred vision, irregular or fast heartbeat, hypertension.

If any of the side effects gets serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist

5. How to Store Otrivin Menthol 0.1%?

Do not use this medicine after the expiry date which is stated on the carton, label after EXP. The expiry date refers to the last day of that month. This date applies even if the packaging has been opened.

Don't store above 25°C. Protect from Heat.
Medicinal products should be kept out of the reach and sight of children.
* Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the Pack and other Information:

- What Otrivin Menthol 0.1% contains?

* The active substance of Otrivin Menthol 0.1% nasal solution is xylometazoline hydrochloride. Each ml contains 1 mg of xylometazoline hydrochloride. Each metered dose Spray delivers 0.14 ml per actuation (0.14 mg of Xylometazoline Hydrochloride)

The preparation contains the following excipients:
Benzalkonium chloride (preservative), Sodium dihydrogen phosphate dihydrate, Disodium phosphate dodecahydrate, Sodium chloride, Disodium edetate, Levomenthol, Cineol, Sorbitol, Polyoxyl hydrogenated castor oil (Cremophor RH 40), Purified Water.

- What Otrivin Menthol 0.1% look like and the content of the pack?

Nasal metered-dose spray: High density polyethylene bottle mounted with a metered-dose pump (materials in contact with the solution: low density polyethylene, high density polyethylene, polyethylene / butyl, stainless steel) and a polypropylene nozzle with a protective cap. Content of the pack: 10 ml.

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MAH: GSK Consumer Healthcare Schweiz AG, Switzerland.



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This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacist