



Patient Information Leaflet (PIL)

Otrivin

Xylometazoline Hydrochloride

Otrivin 0.1% (each ml contains 1 mg Xylometazoline Hydrochloride)
Otrivin 0.1% Metered-Dose Nasal Spray
Otrivin 0.1% Nasal Drops

Otrivin 0.05% (each ml contains 0.5 mg Xylometazoline Hydrochloride)
Otrivin 0.05% Metered-Dose Nasal Spray
Otrivin 0.05% Nasal drops

* Otrivin Nasal Drops and Metered Dose Nasal Sprays are for Nasal administration ONLY

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.

In this leaflet

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1. What Otrivin is and what it is used for?

Otrivin 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. The action of Otrivin is felt within a few minutes and lasts for several hours. Otrivin contains ingredients which help prevent the nasal mucosa drying out.

* Otrivin 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?

a. Do not use Otrivin 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 is not suitable for you in these circumstances.

b. Warnings and precautions

Talk to your doctor or pharmacist before using Otrivin if:

- You have high blood pressure.
 - You suffer from a heart disease.
 - 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 before talking to your doctor or pharmacist.
- Like other products for the relief of blocked nose, Otrivin 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 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 is not intended for use in the eyes or mouth.
 - Do not exceed the recommended dosage, especially in children and in the elderly.
 - Otrivin 0.1% should not be used for children below 12 years of age.
 - Otrivin 0.05% should not be used in children under 1 year of age.

c. Taking Other medicines with Otrivin:

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 if you are taking:

- * Certain medicines used for treatment of depression. These medicines are:
 - Monoamine oxidase inhibitors (MAOI): do NOT use Otrivin 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.

d. Pregnancy and breast-feeding

Otrivin should not be used during pregnancy.

- The use of Otrivin while breast-feeding should only take place on the instructions of a doctor.
- Fertility: There are no relevant data on the effect of Otrivin 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?

* Otrivin Nasal Drops and Metered Dose Nasal Sprays are for Nasal administration ONLY.

* Do not get Otrivin in the mouth or eyes.

* Do not exceed the recommended dose, especially in children and the elderly.

* It is recommended to make the last application shortly before going to bed.

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

* Always use Otrivin exactly as recommended below. You should check with your doctor or pharmacist if you are not sure.

Product	Dose	Age
Otrivin 0.05% Nasal Drops	1-2 drops of 0.05% solution, 1-2 times a day in each nostril are usually sufficient. Do not exceed 3 applications per day.	Children Under 1 year of age: should NOT use the product Children between 1 and 2 years old: only use as prescribed by a doctor
Otrivin 0.05% Metered Dose Nasal Spray	1 spray puff with the 0.05% metered-dose spray 1-2 times a day in each nostril are usually sufficient. Do not exceed 3 applications per day.	Children between 2 and 11 years old: only use under adult supervision.
Otrivin 0.1% Nasal Drops	2-3 drops of 0.1% solution, in each nostril. Repeat as needed, generally 3-4 applications per day are sufficient.	Not to be used for Children under 12 years of age
Otrivin 0.1% Metered Dose Nasal Spray	1 spray puff in each nostril. No more than 3 times per day.	Only for adults and adolescents aged 12 years and over

- If you forget to use Otrivin:
 - 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 Drops:

1. Clear your nose/your child's nose gently.
2. Before using, practice using the dropper to develop good dosage control.
3. Tilt your head/your child's head back as far as is comfortable or, if lying on a bed, hang the head over the side.
4. Without touching the dropper to the nose, apply the drops into each nostril and keep the head tilted back for a short time to allow the drops to spread throughout the nose.



5. If the drop completely misses your nose, administer the drop again.
6. If any part of the drop gets into your nose, do not administer the drop again.
7. Repeat with the other nostril.
8. Clean and dry the dropper before replacing it back into the bottle right after use.
9. To avoid possible spread of infection, the bottle should only be used by one person.

• Instruction for using Otrivin Metered Dose Nasal Spray:

1. Do not cut the nozzle. The metered dose spray is ready to prime before use.
2. Clear your nose/your child's nose gently.
3. Remove protective cap.
4. Before using for the first time, prime the pump by performing a few pumping motions until an even spray is released into the air. At subsequent applications the dosing spray pump will be ready for instant use. 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.



6. Lean forward slightly and insert the nozzle into the nostril.
7. Spray and breathe in gently through the nose at the same time.



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 can cause side effects, although not everybody gets them. STOP using Otrivin 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, nausea, headache, local burning sensation.

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, drug-induced swelling of the nasal mucosa (rhinitis medicamentosa).

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?

The medicinal product must not be used beyond the date which appears after the letters "-EXP-" on the container.

Don't store above 30°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 contains?

* Active Ingredient:

Otrivin 0.1% (each ml contains 1mg of Xylometazoline Hydrochloride)

- Otrivin 0.1% Metered-Dose Nasal Spray:

Each metered dose Spray delivers 0.14 ml per actuation (0.14 mg of Xylometazoline Hydrochloride)

- Otrivin 0.1% Nasal Drops:

Each drop delivers 0.025 mg of Xylometazoline Hydrochloride

Otrivin 0.05% (each ml contains 0.5 mg of Xylometazoline Hydrochloride)

- Otrivin 0.05% Metered-Dose Nasal Spray:

Each metered dose spray delivers 0.07 ml per actuation (0.035 mg of Xylometazoline Hydrochloride).

- Otrivin 0.05% Nasal drops:

Each drop delivers 0.0125 mg of Xylometazoline Hydrochloride.

* The products contain the following Excipients:

Benzalkonium chloride (as a preservative), sodium dihydrogen phosphate dihydrate, Disodium phosphate dodecahydrate, disodium edetate, sodium chloride, sorbitol 70% (non crystallising), methylhydroxypropylcellulose 4000 MPa.s, purified water.

- What Otrivin look like and the content of the pack?

Otrivin 0.1% Nasal Drops and Otrivin 0.05% Nasal Drops:

- Clear solution in a bottle with pipette.

- The content of the pack is 10 ml.

Otrivin 0.1% Metered-Dose Nasal Spray and Otrivin 0.05% Metered Dose Nasal Spray:

- Clear solution in a bottle with a pump delivering just the right amount of product.

- The content of the pack is 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