

Information intended for patients

Read all of this leaflet carefully before you start using Otrivin. 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. Ask a doctor or a pharmacist if you need more information or advice. Keep this leaflet, you may need to read it again. 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.



What is Otrivin and when is it used?

Otrivin contains the active substance xylometazoline. It quickly decongests your stuffy nose and helps clearing blocked mucus secretions so you can breathe easier. 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 2 minutes and lasts for several hours. Otrivin contains ingredients which help prevent the nasal mucosa from drying out. Otrivin 0.1% is indicated in adults and in adolescents over 12 years of age.

When must Otrivin 0.1% not be used?

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 0.1% is not suitable for you in these circumstances.

Warnings and precautions

Do not use Otrivin 0.1% before talking to your doctor or pharmacist if any of the below apply:

- 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 rare tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (pheochromocytoma)
- you are taking certain medicines used for treatment of depression. These medicines are:
 - Monoamine oxidase inhibitors (MAOI): do NOT use Otrivin 0.1% if you are taking or have been taking MAOIs within the last 14 days,
 - tri-cyclic and tetra-cyclic antidepressants,

Like other products for the relief of blocked nose, Otrivin 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 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 0.1% is not recommended for use in children below 12 years of age. Please inform your doctor, pharmacist or chemist if:

- you suffer from another medical condition,
- you are allergic,
- you are already taking or using other medicinal products either internally or externally (even when as self-medication!).

Can Otrivin be used during pregnancy or when breast-feeding?

Do not use Otrivin during pregnancy.

If you are breast-feeding, Otrivin should be used only if recommended by your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

How should Otrivin be used?

Unless otherwise prescribed by the doctor, always give Otrivin exactly as recommended below. Do not exceed the recommended dosage, especially in children and the elderly. You should check with your doctor or pharmacist if you are not sure.

Otrivin 0.1%

Otrivin 0.1% is not recommended for use in children below 12 years of age.

Nasal drops

Age	Posology
Adults and adolescents over 12 years of age	2 to 4 drops into each nostril, up to 3 times daily as needed. Do not exceed 3 applications daily into each nostril. It is recommended to make the last application shortly before retiring to bed.

1. Clear your nose.
2. Before using, practice using the dropper to develop good dosage control.
3. Tilt your 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

Nasal spray (squeeze bottle)

Age	Posology
Adults and adolescents over 12 years of age	1 spray into each nostril, up to 3 times daily as needed. Do not exceed 3 applications daily into each nostril. It is recommended to make the last application shortly before retiring to bed.

To produce a fine spray, the squeeze bottle should be held upright with the nozzle pointing upwards. Be careful not to spray in the eyes.

1. Clear your nose.
2. Remove protective cap.
3. Lean forward slightly and insert the nozzle into a nostril.
4. Squeeze the bottle once and breathe in gently at the same time.
5. Remove the nozzle before releasing the pressure on the bottle.
6. Repeat with the other nostril.
7. Clean and dry the nozzle before replacing back the cap right after use.
8. To avoid possible spread of infection, the spray should only be used by one person.



Please keep to the doses which appear in the package leaflet or prescribed by your doctor. If you feel that the medicinal product is not effective enough or on the contrary, it is too effective, please consult your doctor or pharmacist.

What side-effects can Otrivin cause?

Like all medicines, Otrivin can cause side effects, although not everybody gets them. STOP using Otrivin and seek medical help immediately if you have:

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, difficulty breathing or swallowing, swelling of the face, lips, tongue or throat) blurred vision, irregular or fast heartbeat. 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.

Otrivin 0.1% has no effect on the ability to drive and use machines.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

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Will Otrivin interact with other drugs?

If used as recommended, systemic effects are negligible. However, some systemic effects of Otrivin may be enhanced, particularly in the event of overdose, by concomitant use of tricyclic or tetracyclic antidepressants, MAO inhibitors or other medicinal products with the potential to increase blood pressure.

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 0.1% 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
- If you use any of the above medicines, consult a doctor before using Otrivin.

What happens when there is overdose?

If you use too much Otrivin 0.1% or in case of accidental ingestion, contact your doctor or pharmacist immediately. Do not take a double dose to make up for a forgotten one. No cases of overdose in adults have been reported to date. In rare cases of accidental poisoning in children, the main symptoms may include accelerated and irregular pulse, elevated blood pressure and possibly clouding of consciousness. Symptomatic treatment under medical supervision is indicated.

What else should you bear in mind?

Do not use Otrivin 0.1% after the expiry date which is stated on the outer pack and on the immediate container. The expiry date refers to the last day of that month.

Store in the original package. Store below 30°C. Keep all medicines out of the reach and sight of children.

For more in-depth information, consult your doctor or pharmacist who have access to detailed information for health-care professionals.

What does Otrivin contain?

Squeeze bottle nasal spray, and nasal drops for adults contain 0.1% of xylometazoline hydrochloride.

Where can you obtain Otrivin 0.1%?

What pack sizes are available on the market?

In pharmacies, without medical prescription:
0.1% Nasal spray: 10 ml. 0.1% Nasal drops: 10 ml

Not all of these forms are available in all countries.

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