

Package leaflet: Information for the patient

Otrivine Congestion Relief 0.1% w/v Nasal Spray xylometazoline hydrochloride

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to use Otrivine Congestion Relief Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if the symptoms worsen or do not improve after 7 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

In this leaflet:

1. What Otrivine Congestion Relief Nasal Spray is and what it is used for
2. What you need to know before you use Otrivine Congestion Relief Nasal Spray
3. How to use Otrivine Congestion Relief Nasal Spray
4. Possible side effects
5. How to store Otrivine Congestion Relief Nasal Spray
6. Contents of the pack and other information

1. What Otrivine Congestion Relief Nasal Spray Is and What It Is Used For

Otrivine Congestion Relief Nasal Spray is for application in the nose to give relief from:

- nasal congestion (blocked nose, including colds)
- perennial and allergic rhinitis (recurring inflammation of the nasal mucous membranes, including hay fever)
- sinusitis.

Otrivine Congestion Relief Nasal Spray contains the active ingredient xylometazoline hydrochloride which helps to open up and clear the nasal passages by reducing the excessive nasal secretions and returning the swollen blood vessels to their normal size.

2. What You Need To Know Before You Use Otrivine Congestion Relief Nasal Spray

DO NOT use the spray if you:

- are allergic to xylometazoline hydrochloride or any of the other ingredients in the spray (see Section 6).
Symptoms include: rash, swelling of the face and throat, difficulty breathing.
- are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs)
- have an overactive thyroid gland (hyperthyroidism)
- have acute heart disease
- have undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)
- have narrow angle glaucoma (increased pressure in eyes)
- 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.

Take special care with Otrivine Congestion Relief Nasal Spray

Before using the spray tell your doctor or pharmacist if you:

- have high blood pressure
- suffer from a heart disease (e.g. long QT syndrome)
- suffer from diabetes mellitus

- have an enlarged prostate gland (prostatic hypertrophy)
- are taking medicines for depression called tri or tetra-cyclic antidepressants (see Other medicines and Otrivine Congestion Relief Nasal Spray).
- have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma)

Like other products for the relief of blocked nose, this product can give rise to sleep disturbances, dizziness and tremor in very sensitive individuals. Consult your doctor if these symptoms have proven troublesome to you.

Keep away from the eyes and mouth.

Do not use this spray for children under 12 years old.

Do not take decongestants for more than 7 days in a row. Prolonged or excessive use may cause the stuffiness in the nose to return or worsen.

Other medicines and Otrivine Congestion Relief Nasal Spray

Please tell your doctor or pharmacist before using this product if you are taking, have recently taken or might take any other medicines.

Do not take Otrivine Congestion Relief Nasal Spray with monoamine oxidase inhibitors (e.g. tranlycypromine, phenelzine and isocarboxazid) as this may result in a dangerously high increase in blood pressure (See Section 2 'Do not use...').

Taking Otrivine Congestion Relief Nasal Spray with some medicines may cause an increase in blood pressure and is not recommended. These include:

- Blood pressure tablets (e.g. beta blockers such as propranolol, metoprolol)
- Tricyclic and tetracyclic anti-depressants (e.g. amitriptyline, clomipramine, amoxapine, loxapine).

Pregnancy or breast-feeding

If you are pregnant or breast-feeding, consult your doctor before using Otrivine.

Driving and using machines

Otrivine has very little or no effect on your ability to drive or use machines. If you have blurred vision then do not drive or operate machines.

Important information about some of the ingredients of Otrivine Congestion Relief Nasal Spray

Otrivine Congestion Relief Nasal Spray contains benzalkonium chloride which may cause nasal irritation, difficulty in breathing or wheezing.

3. How to use Otrivine Congestion Relief Nasal Spray

Dosage:

For adults and children over 12 years of age:

1 to 2 sprays into each nostril, 3 times daily as needed. Do not exceed 3 applications daily into each nostril. The last dose can be applied before going to bed.

**Administration:**

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

1. Blow your nose gently.
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.

To avoid possible spread of infection, this pack should only be used by one person. For reasons of hygiene do not use this bottle for more than 28 days after opening it.

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

If you use more Otrivine Congestion Relief Nasal Spray than you should or accidentally swallow it, consult your doctor or pharmacist immediately.

4. Possible side effects

Like all medicines, Otrivine Congestion Relief Nasal Spray can cause side effects, although not everybody gets them. Local discomfort may be felt after applying the spray if you have sensitive nasal passages.

STOP using Otrivine Congestion Relief Nasal Spray and **seek medical help immediately** if you have any of the following

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

Common side effects (may affect up to 1 in 10 people)

Dryness or irritation of the nasal mucosa, nausea, headache or local burning sensation.

Uncommon side effects (may affect up to 1 in 100 people)

Nosebleeds

Very rare side effects (may affect up to 1 in 10,000 people)

Allergic reaction (skin rash, itching), temporary or passing blurred vision, irregular or fast heartbeat.

Cardiovascular effects, for example, palpitations, may also occur especially if you have heart problems.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the HPRA Pharmacovigilance website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otrivine Congestion Relief Nasal Spray

Keep out of the sight and reach of children.

Do not use after the expiry date which is stated on the bottle after “EXP”.

The expiry date refers to the last day of that month.

Do not store above 25 °C.

Keep bottle in outer carton.

Do not use this bottle for more than 28 days after opening it.

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 Otrivine Congestion Relief Nasal Spray contains

The **active** ingredient is xylometazoline hydrochloride (0.1% w/v, 1 mg/ml).

The **other** ingredients are Benzalkonium chloride, Disodium phosphate dodecahydrate (Sodium phosphate), Disodium edetate, Sodium dihydrogen phosphate dihydrate (Sodium acid phosphate), Sodium chloride, Purified water.

What Otrivine Congestion Relief Nasal Spray looks like and the contents of the pack

Clear aqueous solution in a 10 ml bottle.

Marketing Authorisation Holder

Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer

Haleon Germany GmbH or GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Barthstrasse 4, D-80339 Munich, Germany

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