

Package leaflet: Information for the patient
Otrivine Congestion Relief Menthol 0.1% w/v Nasal Spray
xylometazoline hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without a prescription. However, you still need to use Otrivine Congestion Relief Menthol 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See Section 4.
- You must talk to a doctor if the symptoms worsen or do not improve after 7 days.

In this leaflet:

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

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

Otrivine Congestion Relief Menthol 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 Menthol 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 Menthol 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 the 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

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

- have high blood pressure, heart (e.g. long QT syndrome) or circulatory disease
- have diabetes mellitus
- have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma)
- 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 Menthol)

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, as prolonged or excessive use may cause stuffiness in the nose to return or worsen.

Other medicines and Otrivine Congestion Relief Menthol

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 Menthol with monoamine oxidase inhibitors (e.g. tranylcypromine, 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 Menthol 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 other ingredients:

This medicine contains polyoxyl hydrogenated castor oil (2.750 mg/ml) which may cause skin reactions.

3. How to use Otrivine Congestion Relief Menthol Nasal Spray**Before first use**

Prime the pump by pumping 5 times. Once primed the pump will normally remain charged throughout regular daily treatment periods.

For adults and children over 12 years of age:

one spray in each nostril up to 3 times daily as needed.

Administration:

Remove cap.

Be careful not to spray in the eyes and mouth.

1. Clear the nose.
2. Hold the bottle with thumb on the actuation button.
3. For a no dripping effect, stay upright and insert the short nozzle into a nostril.
4. Press on the button to spray and breathe in gently through the nose at the same time. Repeat this procedure (steps 2 to 4) in the other nostril.
5. After each use, clean and dry the nozzle.
6. Put the protective cap back on until an audible “click” is heard.



1. Clear nose



2. Thumb on button



3. Insert in nose



4. Press button



5. Clean and dry



6. Replace cap

Should the spray not be 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 re-primed with 2 pumps.

If the full spray is not administered, the dose should not be repeated.

To avoid possible spread of infection, this pack should only be used by one person.

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

If you use more Otrivine Congestion Relief Menthol Nasal Spray than you should, consult your doctor or pharmacist.

If you forget to use Otrivine Congestion Relief Menthol Nasal Spray.

Do not take a double dose to make up for a forgotten one.

4. Possible side effects

Like all medicines, Otrivine Congestion Relief Menthol 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 Menthol Nasal Spray 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.

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

- Dryness or irritation of the nasal mucosa, nausea, headache, 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 reactions (skin rash, itching), blurred vision, irregular or fast heartbeat.

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 Menthol Nasal Spray

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date which is stated on the bottle and carton after 'EXP'.

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

Do not store above 25 °C.

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 Menthol Nasal Spray contains

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

The **other ingredients** are: sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sodium chloride, disodium edetate, levomenthol (menthol), cineole (eucalyptol), sorbitol, polyoxylhydrogenated castor oil (macrogol glycerol hydroxystearate) and purified water.

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

White aqueous solution in a 10ml bottle.

Marketing Authorisation Holder:

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland.

Manufacturer:

Haleon Germany GmbH, Barthstraße 4, 80339 München, Germany

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