

Otrivine

Congestion Relief 0.1% 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 0.1% 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 any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Otrivine Congestion Relief 0.1% Nasal Spray is and what it is used for
2. What you need to know before you use Otrivine Congestion Relief 0.1% Nasal Spray
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1. What Otrivine Congestion Relief 0.1% Nasal Spray is and what it is used for

Otrivine Congestion Relief 0.1% 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 0.1% 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 0.1% 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)
- have had recent neurosurgery
- have narrow angle glaucoma
- have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis)

- have an enlarged prostate gland
- have a rare tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma)
- are taking monoamine oxidase inhibitors (MAOIs) or have stopped taking them in the last 14 days.

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

Take special care

Before using the spray tell your doctor if you:

- have an overactive thyroid gland (hyperthyroidism)
- have diabetes mellitus
- have a heart or circulatory disease (e.g. long QT syndrome)
- are pregnant or breastfeeding
- have high blood pressure
- are taking tri and tetra-cyclic antidepressant treatment

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

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

Using other medicines:

Please tell your doctor or pharmacist before using this product if you are taking or have recently taken any medicines (especially monoamine oxidase inhibitors or other antidepressants) including those obtained without a prescription.

Pregnancy or breastfeeding:

If you are pregnant or breastfeeding, consult your doctor before using Otrivine. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery:

Otrivine has very little or no effect on your ability to drive or use machines.

Important information about some of the other ingredients:

The medicine contains polyoxylhydrogenated castor oil (2.750 mg/ml) which may cause skin reactions.

3. How to use Otrivine Congestion Relief 0.1% Nasal Spray

Dosage:

For adults and children over 12 years of age:

One spray in each nostril up to 3 times daily. Do not exceed 3 applications daily into each nostril.

Administration:

- Remove protective cap.
- Before using for the first time, prime the pump by actuating 5 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 re-primed with 2 actuations.

To remove the cap, press and twist on the two marks. Be careful not to spray in the eyes.

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.



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 0.1% Nasal Spray than you should, consult your doctor or pharmacist immediately.

If you forget to use Otrivine Congestion Relief 0.1% 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 0.1% Nasal Spray can cause side effects, although not everybody gets them.

Stop using Otrivine Congestion Relief 0.1% Nasal Spray and **seek medical help immediately** if you experience:

- Allergic reactions which may include difficulty breathing or swallowing, swelling of the face, lips, tongue and throat, severe itching of the skin, with a red rash or raised bumps.

Common (may affect up to 1 in 10 people):

- Headache
- Nasal dryness
- Nasal discomfort
- Nausea
- Local irritation after using the spray

Uncommon (may affect up to 1 in 100 people):

- Nosebleeds

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

- Hypersensitivity including rash and pruritus
- Disturbances of vision
- Palpitations and increased heart rate

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otrivine Congestion Relief 0.1% 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. Store in the original package. 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 0.1% Nasal Spray contains

The **active ingredient** is xylometazoline hydrochloride (0.1% w/v).

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

What Otrivine Congestion Relief 0.1% Nasal Spray looks like and the contents of the pack

Otrivine Congestion Relief 0.1% Nasal Spray is a white solution in a 10 ml bottle.

Marketing Authorisation Holder:

Haleon UK Trading Limited, Weybridge, KT13 ONY, U.K.

Manufacturer:

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

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