

Otrivine Adult Menthol 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 Adult 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.

—You must contact a doctor if the symptoms worsen or do not improve after 7 days.

—If any of the side effects gets 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 Adult Menthol Nasal Spray is and what it is used for
2. Before you use Otrivine Adult Menthol Nasal Spray
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1. WHAT OTRIVINE ADULT MENTHOL NASAL SPRAY IS AND WHAT IT IS USED FOR

Otrivine Adult 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 Adult 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. BEFORE YOU USE OTRIVINE ADULT 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 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 Adult Menthol Nasal Spray

Before using the spray tell your doctor if

—you have high blood pressure

—you suffer from heart disease (e.g. long QT syndrome)

—you suffer from diabetes mellitus

—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)

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 the 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.

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 anti-depressants) including those obtained without a prescription.

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.

Pregnancy or breast-feeding

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

Important information about some of the ingredients of Otrivine Adult Menthol Nasal Spray

Contains 0.1 mg benzalkonium chloride in each 1 ml, which may cause irritation or swelling inside the nose, especially if used for a long time. Otrivine Adult Menthol Nasal Spray also contains polyoxyl hydrogenated castor oil which may cause skin reactions.

3. HOW TO USE OTRIVINE ADULT MENTHOL NASAL SPRAY

Dosage:

For Adults and Children over 12 years of age:

1 to 2 sprays in 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.

[Image of person administering spray into nostril]

Administration:

1. To produce a fine spray, the nebuliser should be held upright with the nozzle pointing upwards. Be careful not to spray in the eyes.
2. Blow your nose gently.
3. Remove protective cap.
4. Lean forward slightly and insert the nozzle into a nostril.
5. Squeeze the bottle once and breathe in gently at the same time.
6. Remove the nozzle before releasing the pressure on the bottle.
7. Repeat with the other nostril.
8. 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 Adult Menthol Nasal Spray than you should or accidentally swallow it, consult your doctor or pharmacist immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Otrivine Adult 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 and seek medical help 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 less than 1 in 10 individuals).

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

Uncommon side effects (may affect less than 1 in 100 individuals).

Nosebleeds

Very rare side effects (may affect less than 1 in 10,000 individuals)

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 gets 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 HPRC 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 ADULT MENTHOL 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 "Expiry". The expiry date refers to the last day of that month. Do not use this bottle for more than 28 days after opening it. 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. FURTHER INFORMATION

What Otrivine Adult Menthol 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, Sorbitol liquid non-crystallising (E420), Menthol, Eucalyptol, Polyoxyl hydrogenated castor oil, Purified water.

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

Otrivine Adult Menthol Nasal Spray is a clear, colourless aqueous solution packed in 10 ml bottles.

Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland.

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