

Otrivine

Adult 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 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 Nasal Spray is and what it is used for
2. Before you use Otrivine Adult Nasal Spray
3. How to use Otrivine Adult Nasal Spray
4. Possible side effects
5. How to store Otrivine Adult Nasal Spray
6. Further information

1. WHAT OTRIVINE ADULT NASAL SPRAY IS AND WHAT IT IS USED FOR

Otrivine Adult 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 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 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)

- are allergic to other decongestants
- 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 hypertension
- have heart or circulatory disease (e.g. long QT syndrome)
- have an overactive thyroid gland (hyperthyroidism)
- have diabetes mellitus
- are pregnant or breast-feeding

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 may cause 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 breast-feeding

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

Driving and using machines

Otrivine has no effect on the ability to drive and use machines.

Important information about some of the other ingredients

Otrivine contains benzalkonium chloride which may cause nasal irritation.

3. HOW TO USE OTRIVINE ADULT NASAL SPRAY

Dosage:

For Adults and Children over 12 years of age:

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



Administration:

1. Clear your nose.
2. Lean forward slightly and insert the nozzle into a nostril (see diagram).
3. Squeeze the bottle once and sniff at the same time.
4. Remove the nozzle before releasing the pressure on the bottle.
5. Repeat for the other nostril.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Otrivine Adult Nasal Spray can cause side effects, although not everybody gets them.

Stop using Otrivine Adult 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

Other side effects include:

- A burning sensation in the nose and throat

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 ADULT 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 after "EXP". The expiry date refers to the last day of that month.

Do not store above 25 °C.

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. FURTHER INFORMATION

What Otrivine Adult Nasal Spray contains

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

The **other** ingredients are sodium chloride, sodium phosphate, sodium acid phosphate, disodium edetate, benzalkonium chloride and water.

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

Colourless aqueous solution packed in 10ml bottles.

Marketing Authorisation Holder:

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

Manufacturer:

GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Barthstraße 4, 80339, Munich, Germany or GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

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