Otrivine

Adult Nasal Drops 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 Drops 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:

- What Otrivine Adult Nasal Drops are and what they are used for
- 2. Before you use Otrivine Adult Nasal Drops
- 3. How to use Otrivine Adult Nasal Drops
- Possible side effects
- 5. How to store Otrivine Adult Nasal Drops
- 6. Further information

1. WHAT OTRIVINE ADULT NASAL DROPS ARE AND WHAT THEY ARE USED FOR

Otrivine Adult Nasal Drops are 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 Drops contain 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 DROPS

DO NOT use the drops if you:

 are allergic to xylometazoline hydrochloride or any of the other ingredients in the drops (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 inhibitor (MAOIs) or have stopped taking them in the last 14 days.

Do not use these drops for children under 12 years old.

Take special care

Before using the drops tell your doctor if you:

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

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

Otrivine contains benzalkonium chloride which may cause nasal irritation.

3. HOW TO USE OTRIVINE ADULT NASAL DROPS

Dosage:

For Adults and Children over 12 years of age:

2 to 3 drops in each nostril up to 3 times daily. Do not exceed 3 applications daily into each nostril.



Administration:

- 1. Clear your nose.
- 2. Lean head back as far as is comfortable (see diagram).
- 3. Apply the drops into each nostril and keep head back for a short time.
- 4. Clean and dry the dropper before replacing it back. 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 elderly.

If you use more Otrivine Adult Nasal Drops than you should, consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop using Otrivine Adult Nasal Drops and **seek medical help immediately** if you experience:

 Allergic reactions, which may include difficult 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
- Dryness of the nasal membranes
- Nasal discomfort
- Nausea
- Local irritation after applying the drops

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

Nosebleeds

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

- Blurred vision
- Irregular or fast heartbeat

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 DROPS

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

Protect from heat.

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 Drops contain

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, sorbitol, hypromellose and water.

What Otrivine Adult Nasal Drops look like and the contents of the pack

Otrivine Adult Nasal Drops are a clear, colourless aqueous solution packed in 10 ml bottles.

Marketing Authorisation Holder & Manufacturer GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

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