

Otrivine

Child 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 Child 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 5 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 Child Nasal Drops are and what they are used for
2. Before you use Otrivine Child Nasal Drops
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4. Possible side effects
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1. WHAT OTRIVINE CHILD NASAL DROPS ARE AND WHAT THEY ARE USED FOR

Otrivine Child 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 Child 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 CHILD NASAL DROPS

DO NOT use the drops if your child:

- is under 6 years old
- is allergic to xylometazoline hydrochloride or any of the other ingredients in the drops (see Section 6)
- has an inflamed nasal passage

- is allergic to other decongestants
- has had recent neurosurgery or nasal surgery
- has heart or circulatory disease or hypertension
- has diabetes
- has hyperthyroidism (overactive thyroid gland)
- has closed angle glaucoma
- has an enlarged prostate gland
- has pheochromocytoma (a tumour of the nerves associated with the hormone glands)
- is taking monoamine oxidase inhibitors (MAOIs) or has stopped taking them in the last 14 days
- is taking betablockers
- has chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis)

Do not use these drops in children under 6 years old.

Take special care

Before using the drops tell your doctor if your child:

- is taking any other medicine or is under doctor's care

Like other products for the 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.

If your child experiences hallucinations, restlessness or sleep disturbances stop using Otrivine Child Nasal Drops.

Do not take Otrivine Child Nasal Drops for more than 5 days in a row. Prolonged or excessive use may cause stuffiness in the nose to return or worsen. Keep away from the eyes.

Using other medicines

Do not use these drops if your child is using other decongestants. Please tell your doctor or pharmacist if your child is taking or has recently taken any medicines (especially antidepressants, moclobemide, medicines for high blood pressure or heart problems, appetite suppressants, oxytocin or ergot alkaloids) 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.

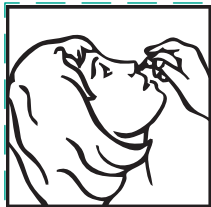
Important information about some of the other ingredients

Otrivine contains benzalkonium chloride which may cause nasal irritation.

3. HOW TO USE OTRIVINE CHILD NASAL DROPS

Dosage:

For children aged 6–12 years, under adult supervision: 1 to 2 drops in each nostril once or twice daily. Not more than 2 doses should be given in any 24 hours.



Do not use in children under 6 years of age.

Administration:

1. Practise using the dropper to develop good dosage control
2. Clear and wipe your child's nose
3. Tilt your child's head right back (see diagram)
4. Apply drops to each nostril as per dosage instructions.

Parents or carers should seek medical attention if the child's condition worsens.

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. Do not take with any other cough and cold medicines.

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

4. POSSIBLE SIDE EFFECTS

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

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

- Allergic reactions which may include difficulty breathing or swallowing
- Swelling of the face, lips, tongue or throat

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

- Headache
- Dryness or irritation of the nasal mucosa
- Nausea
- Local burning sensation

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:

- Hallucinations and paranoid delusions
- Restlessness and sleep disturbances
- A burning sensation in the nose and throat
- Excitability, irritability and anxiety
- Urinary retention
- High blood pressure

- Tolerance with diminished effect & rebound congestion with prolonged use

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effect 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 CHILD 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 Child Nasal Drops contain

The **active** ingredient is xylometazoline hydrochloride (0.05% w/v).

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

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

Clear aqueous solution in a 10ml bottle

Marketing Authorisation Holder and Manufacturer:

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

This leaflet was last revised in June 2021

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