

# Otrivine®

## Child Nasal Drops

### Xylometazoline Hydrochloride

#### Cough and Cold in children

It is usual for children to get several colds a year. As they get older, their immunity builds up and they get fewer colds. Most colds will get better within a few days and you may not need to do more than keep your child comfortable until they get over it.

**Fever:** If they are feverish, give them plenty of fluids to drink. Their temperature may be lowered with a suitable medicine which has doses for children. For further advice, talk to your healthcare professional.

**Coughs:** Although it can be distressing to hear your child cough, in fact this helps to clear phlegm from the chest and mucus from the nose. Give your child plenty of warm clear fluids.

#### 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
3. How to use Otrivine Child Nasal Drops
4. Possible side effects
5. How to store Otrivine Child Nasal Drops
6. Further information

## 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 disease or hypertension
- has diabetes
- has hyperthyroidism (overactive thyroid gland)
- has closed angle glaucoma
- 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

#### Take special care

Before using the drops tell your doctor if your child:

- has heart or circulatory disease
- is taking any other medicine or is under doctor's care

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. 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.

## 3. HOW TO USE OTRIVINE CHILD NASAL DROPS

#### Dosage:

##### For children aged 6–12 years:

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.  
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.

Local discomfort may be felt after applying the drops if you have sensitive nasal passages.

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

**Occasionally** the following side effects have been reported:

- A burning sensation in the nose and throat
- local irritation
- nausea
- headache
- dryness of the nasal membranes.

Palpitations, changes in heart rhythm or increased blood pressure 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.**

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Alternatively you can call Freephone 0800 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

#### 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

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

##### Marketing Authorisation Holder

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

##### Manufacturer

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

##### This leaflet was last revised in January 2016

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