

**Information intended for patients**

Read all of this leaflet carefully before you start using Otrivin. It contains important information for you. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Ask a doctor or a pharmacist if you need more information or advice. Keep this leaflet, you may need to read it again. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You must talk to a doctor if you do not feel better or if you feel worse.

**What is Otrivin and when is it used?**

Otrivin contains the active substance xylometazoline. It quickly decongests your child's stuffy nose and helps clearing blocked mucus secretions so your child can breathe easier.

Otrivin is used for various types of colds. It is designed to be applied in the nostrils, where it exerts a vasoconstricting effect thereby decongesting the mucosae of the nose and the throat.

This effect allows patients with colds to breathe more easily through the nose. The action of Otrivin is felt within 2 minutes and lasts for several hours. Otrivin contains ingredients which help prevent the nasal mucosa from drying out.

Otrivin 0.05% is indicated in children aged 2 to 11 years old.

**When must Otrivin 0.05% not be used?****Do not use Otrivin if your child:**

- is allergic to xylometazoline or any other ingredients of this medicine
- has undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)
- has narrow angle glaucoma (increased pressure in eyes)
- has chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis)

Tell your doctor or pharmacist if any of the above apply because Otrivin 0.05% is not suitable for your child in these circumstances.

**Warnings and precautions**

Do not use Otrivin 0.05% before talking to your doctor or pharmacist if any of the below apply:

The patient

- Has high blood pressure
- suffers from a heart disease
- has an overactive thyroid gland (hyperthyroidism)
- suffers from diabetes

- has a rare tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (pheochromocytoma)
- is taking certain medicines used for treatment of depression. These medicines are:
  - Monoamine oxidase inhibitors (MAOI): do NOT use Otrivin 0.05% if your child is taking or have been taking MAOIs within the last 14 days,
  - tri-cyclic and tetra-cyclic antidepressants.

Like other products for the relief of blocked nose, Otrivin 0.05% may give rise to sleep disturbances, vision problems, dizziness, tremor in very sensitive patients. Consult your doctor if such signs prove troublesome.

Like other nasal decongestants, Otrivin 0.05% should not be used for more than 7 consecutive days. If symptoms persist, consult your doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen.

Otrivin 0.05% should not be used in children aged less than 2 year. It is recommended for use in children aged 2 to 11 years only under adult supervision.

Please inform your doctor or pharmacist if your child:

- suffers from another medical condition,
- is allergic,
- is already taking or using other medicinal products either internally or externally (even when as self-medication!).

**Can Otrivin be used during pregnancy or when breast-feeding?**

Do not use Otrivin during pregnancy.

If you are breast-feeding, Otrivin should be used only if recommended by your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

**How should Otrivin be used?**

Unless otherwise prescribed by the doctor, always give Otrivin exactly as recommended below. Do not exceed the recommended dosage, especially in children and the elderly. You should check with your doctor or pharmacist if you are not sure.

**Otrivin 0.05%**

- should not be used in children aged less than 2 year old,
- is recommended for use in children aged 2 to 11 years old only under adult supervision. Do not exceed 3 applications daily into each nostril. It is recommended to make the last application shortly before retiring to bed. The usual doses are as follows:

| Age                           | Posology                                                                                                                    |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Children 2 to 5 years of age  | With adult supervision, 1 to 2 drops into each nostril once or twice daily, (every 8 to 10 hours) are generally sufficient. |
| Children 6 to 11 years of age | With adult supervision, 2 to 4 drops into each nostril, 2 to 3 times daily as needed.                                       |

1. Gently clear your child's nose.
2. Before using, practice using the dropper to develop good dosage control.
3. Tilt your child's head slightly back, as far as is comfortable, or if lying on a bed, hang the head over the side.
4. Without touching the dropper to the nose, very carefully apply the drop(s) into each nostril and keep the head tilted back for a short time to allow the drops to spread throughout the nose.
5. If the drop completely misses the child's nose, administer the drop again.
6. If any part of the drop gets into the nose, do not administer the drop again.
7. Repeat with the other nostril.
8. Clean and dry the dropper before replacing it back into the bottle right after use.
9. To avoid possible spread of infection, the bottle should only be used by one person.



Please keep to the doses which appear in the package leaflet or prescribed by your doctor. If you feel that the medicinal product is not effective enough or on the contrary, it is too effective, please consult your doctor or pharmacist.

#### What side-effects can Otrivin cause?

Like all medicines, Otrivin can cause side effects, although not everybody gets them. STOP using Otrivin and seek medical help immediately if the patient has:

**Common side effects** (may affect up to 1 in 10 people): Dryness or irritation of the nasal mucosa, nausea, headache, local burning sensation.

**Very rare side effects** (may affect less than 1 in every 10,000 people):

Allergic reactions (skin rash, itching, difficulty breathing or swallowing, swelling of the face, lips, tongue or throat), blurred vision, irregular or fast heartbeat.

If any of the side effects gets serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### Reporting of side effects

If your child is getting any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

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#### Will Otrivin interact with other drugs?

If used as recommended, systemic effects are negligible. However, some systemic effects of Otrivin may be enhanced, particularly in the event of overdose, by concomitant use of tricyclic or tetracyclic antidepressants, MAO inhibitors or other medicinal products with

the potential to increase blood pressure.

Tell your doctor or pharmacist if your child is taking, have recently taken or might take any other medicines.

In particular, you should not give Otrivin 0.05% if your child is taking certain medicines used for treatment of depression. These medicines are:

- Monoamine oxidase inhibitors (MAOI): do NOT use Otrivin if your child is taking or has been taking MAOIs within the last 14 days
- Tri-cyclic and tetra-cyclic antidepressants

If you give any of the above medicines to your child, consult a doctor before using Otrivin.

#### What happens when there is overdose?

If the patient uses too much Otrivin 0.05% or in case of accidental ingestion, contact your doctor or pharmacist immediately. Do not take a double dose to make up for a forgotten one. No cases of overdose in adults have been reported to date. In rare cases of accidental poisoning in children, the main symptoms may include accelerated and irregular pulse, elevated blood pressure and possibly clouding of consciousness. Symptomatic treatment under medical supervision is indicated.

#### What else should you bear in mind?

Do not use Otrivin 0.05% after the expiry date which is stated on the outer pack and on the immediate container. The expiry date refers to the last day of that month.

Store in the original package.

Store below 30°C. Keep all medicines out of the reach and sight of children.

For more in-depth information, consult your doctor or pharmacist who have access to detailed information for healthcare professionals.

#### What does Otrivin contain?

Nasal drops for children contain 0.05% of xylometazoline hydrochloride, and benzalkonium chloride as a preservative.

#### Where can you obtain Otrivin 0.05%?

#### What pack sizes are available on the market?

In pharmacies, without medical prescription:  
0.05% nasal drops: 10 ml.

**Not all of these forms are available in all countries.**

Information updated: October 2018

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NPA002956



Pharma code XXXX