



Otrivin®

Nasal drops, nasal gel, metered-dose nasal spray
Local vasoconstrictor for nasal decongestion

Information intended for patients

Read all of this leaflet carefully before you start using Otrivin. It contains important information for you. Follow the instructions carefully to get the best results. Ask a doctor or a pharmacist if you need more information or advice. Keep this leaflet, you may need to read it again.

What is Otrivin and when is it used?

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 a few minutes and lasts for several hours. Otrivin contains ingredients which help prevent the nasal mucosa drying out. Thanks to its prolonged action, the gel formulation is particularly indicated for facilitating nasal breathing during the night.

When must Otrivin not be used?

If you have had surgery involving the head, it is up to your doctor to decide whether you can use Otrivin. This limitation also applies to all other vasoconstrictive products used in the nose. Otrivin must not be used in the case of dry nasal mucosa (rhinitis sicca) or in the case of acute (closed-angle) glaucoma. Patients who are allergic to any of the ingredients in Otrivin must not use this medicinal product.

What precautions must be taken when using Otrivin?

As with other medicinal products for colds, Otrivin can lead to sleep and vision problems or episodes of dizziness which are evidence of oversensitivity to the product. Please consult your doctor if

- these effects are very disruptive,
- your cold persists or gets worse or
- other problems appear.

Otrivin must be used with care in the case of hypertension, cardio-vascular disease, thyroid hyperactivity or diabetes (Diabetes mellitus).

Otrivin must not be used for more than a week without medical advice because over a longer period of use, rebound congestion of the nasal mucosa (rhinitis medicamentosa) may appear. This would be very similar to the symptoms of a cold. Do not use the 0.1% drops, nebuliser, metered-dose spray or gel in children under 6 years old.

The Otrivin 0.05% nasal drops and metered-dose spray must not be used without a medical prescription in children under 2 years old and must be administered under adult supervision in children under 6 years old.

Please inform your doctor, pharmacist or chemist if:

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

Can Otrivin be used during pregnancy or when breastfeeding?

If you are pregnant or breast-feeding, please consult your doctor before using Otrivin.

How should Otrivin be used?

Unless otherwise prescribed by the doctor, you must keep to the following dosage recommendations: Infants and children under 2 years old, only under medical prescription, and children under 6 years old under adult supervision: 0.05% nasal drops and metered-dose spray:

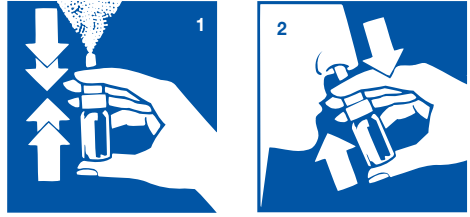
1-2 drops of solution or 1 spray puff with the 0.05% metered-dose spray 1-2 times a day in each nostril are usually sufficient. Do not exceed 3 applications per day.

Adults and children over 6 years: 0.1% nasal drops, nebuliser and metered-dose spray: 2-3 drops of solution or 1 spray puff from 0.1% nebuliser or metered-dose spray in each nostril; generally 4 applications per day are sufficient. Gel: Apply a small amount of gel as deeply as possible into each nostril 3-4 times per day. The last application will usually take place shortly before bedtime. In children under 6 years, only the 0.05% nasal drop solution or metered-dose spray should be used.

Method for using the metered-dose spray:

Metered-dose spray (without gas propellant):

Remove protective cap. Before using for the first time, pump several times (fig.1) until an even mist appears. Place the nozzle of the device in the nostril and exert pressure firmly, once only, on the collar of the metered-dose spray (fig.2).



For subsequent applications, the metered-dose spray is instantly ready for use without prior pumping. Nebuliser: Place the nozzle of the device in the nostril and exert pressure firmly, once only, on the sides of the nebuliser, remove the nozzle before releasing the pressure. Inhaling slightly through the nose when pressure is applied ensures optimal dispersion of the nebuliser mist. Replace the protective cap after use. 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, pharmacist or chemist.

What side-effects can Otrivin cause?

Using Otrivin can cause the following side-effects: occasionally, a burning sensation in the nose and throat, local irritation, nausea, headaches and dryness of the nasal mucosa. In very rare cases insomnia or allergic reactions with respiratory problems may also appear. If you notice side-effects that are not mentioned in this leaflet, please tell your doctor, pharmacist or chemist.

What else should you bear in mind?

The medicinal product must not be used beyond the date which appears after the letters «EXP» on the container.

Otrivin gel: for hygiene reasons, use Otrivin gel within 1 month after first opening of the packaging.

Don't store above 30°C. Medicinal products should be kept out of the reach of children.

For more in-depth information, consult your doctor, pharmacist (especially with regard to the 0.05% nasal drops and metered-dose spray for children under 6 years old) or chemist, who have access to detailed information for healthcare professionals.

What does Otrivin contain?

Metered-dose spray, gel, nebuliser and nasal drops for adults contain 0.1% of xylometazoline hydrochloride, nasal drops and metered-dose spray for children contain 0.05% of xylometazoline hydrochloride, and benzalkonium chloride as a preservative.

The gel also includes flavoring substances. 1 spray puff from the metered-dose spray corresponds to 0.14 mg (0.1%) and 0.035 mg (0.05%) respectively of xylometazoline hydrochloride.

Where can you obtain Otrivin?

What pack sizes are available on the market?

In pharmacies, without medical prescription:

0.1% metered-dose spray: 10 ml.

0.1% Gel: 10 g tube

0.1% Nasal drops: 10 ml

0.05% nasal drops: 10 ml.

0.05% metered-dose spray: 10 ml.

Not all of these forms are available in all countries.

Manufacturer:

Novartis Consumer Health SA
Nyon, Switzerland

Information updated: March 2008

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(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists