

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using **OTRIVIN ADULT NASAL DROPS**, **OTRIVIN ADULT NASAL METERED-DOSE SPRAY**, **OTRIVIN PAED. NASAL DROPS** or **OTRIVIN PAED. NASAL METERED-DOSE SPRAY**.

OTRIVIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **OTRIVIN** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **OTRIVIN** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

SCHEDULING STATUS

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

OTRIVIN ADULT NASAL DROPS (1 ml contains 1 mg of xylometazoline hydrochloride).

OTRIVIN ADULT NASAL METERED-DOSE SPRAY (1 ml contains 1 mg of xylometazoline hydrochloride).

OTRIVIN PAED. NASAL DROPS (1 ml contains 0,5 mg of xylometazoline hydrochloride).

OTRIVIN PAED. NASAL METERED-DOSE SPRAY (1 ml contains 0,5 mg of xylometazoline hydrochloride).

1. WHAT OTRIVIN CONTAINS

The active substance in **OTRIVIN** is xylometazoline hydrochloride

Preservative: 0,011 % *m/v* benzalkonium chloride.

The inactive ingredients are: disodium edentate, disodium phosphate dodecahydrate, methylhydroxypropyl-cellulose, purified water, sodium chloride, sodium dihydrogen phosphate dehydrate and sorbitol 70 % (non-crystallising)

2. WHAT OTRIVIN IS USED FOR

OTRIVIN is a nasal decongestant that quickly clears blocked noses. It also contains soothing ingredients that help prevent dryness and irritation of the nasal passages.

OTRIVIN are used for the relief of blocked nose caused by colds, hay fever or other allergic rhinitis, sinusitis.

The effect of **OTRIVIN** starts within minutes and persists for several hours. It is well tolerated, even by patients with a sensitive nasal mucosa.

OTRIVIN may also be used in ear infections to help to decongest the nasopharyngeal mucosa. It may also be prescribed by your doctor in the event of examination of the nose.

3. BEFORE YOU USE OTRIVIN

Do not use OTRIVIN:

- **OTRIVIN ADULT NASAL DROPS and OTRIVIN ADULT NASAL METERED-DOSE SPRAY in children less than 12 years of age.**
- **OTRIVIN PAED. NASAL DROPS and OTRIVIN PAED. NASAL METERED-DOSE SPRAY of 0,05 mg/ml is not recommended for children below 2 years of age.**
- If you are allergic to xylometazoline or to any of the other ingredients of **OTRIVIN**.
- If you suffer from a heart disease characterized by ischaemia (reduced blood supply) to the heart muscle, usually due to coronary artery disease (atherosclerosis of the coronary arteries).

- If you are being treated with medicine known as monoamine oxidase (MAO)- inhibitors (e.g. moclobemide, selegiline) or 10 days after stopping treatment.
- If you have undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)
- If you have narrow angle glaucoma (increased pressure in eyes).
- If you have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis)

Tell your doctor or pharmacist if any of the above apply to you because **OTRIVIN** is not suitable for you in these circumstances.

Take special care with OTRIVIN:

Talk to your doctor or pharmacist before use if any of the below apply:

- if you have high blood pressure, heart disease, overactive thyroid, narrow angle glaucoma or diabetes
- difficulty in urinating and/or enlarged prostate gland
- a tendency to have nose bleeds
- if you have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma) or a particular sensitivity to adrenaline and noradrenaline as you may experience dizziness, tremor, rapid heart rate, raised blood pressure and sleeplessness.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **OTRIVIN** with these medicines may cause undesirable interactions. Tell

your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other health care professional for advice.

It is particularly important to tell your doctor or pharmacist if you are taking any of the following medicines or you have been taking them within the last 14 days:

- Monoamine oxidase inhibitors (MAOI) antidepressants, e.g. moclobemide, selegiline
- Tricyclic (e.g. amitriptyline, clomipramine) or tetracyclic (e.g. mianserin, mirtazapine) antidepressants,

4. HOW TO USE OTRIVIN

Always use **OTRIVIN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure about the dosage. If you have the impression that the effect of **OTRIVIN** is too strong or too weak, talk to your doctor or pharmacist.

Like other nasal decongestants, **OTRIVIN** should not be used for more than 10 consecutive days. If symptoms persist, consult your doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen.

OTRIVIN ADULT NASAL DROPS and OTRIVIN ADULT NASAL METERED-DOSE SPRAY

(1 mg/ml) are for nasal administration only, in adults and children over 12 years of age:

2 to 3 drops of the 1 mg/ml solution into each nostril per application, or one or two applications from the metered-dose spray, into each nostril per application; a total of 3 to 4 applications a day is usually sufficient.

OTRIVIN PAED. NASAL DROPS and OTRIVIN PAED. NASAL METERED-DOSE SPRAY

(0,5 mg/ml) are for nasal administration only, for children of 2 to 12 years of age.

1 to 2 drops of the 0,5 mg/ml solution or one application of the metered-dose spray into each nostril once or twice daily, are generally sufficient; do not exceed a total of 3 applications daily into each nostril.

Instructions for use/handling

Nasal Drops

1. Clear the nose.
2. Tilt the head back as far as is comfortable or, if lying on a bed, hang the head over the side.
3. Apply the drops into each nostril and keep the head tilted back for a short time to allow the drops to spread throughout the nose.
4. Replace cap right after use.

Otrivin Paed Nasal Metered-Dose Spray

1. Do not cut the nozzle. The metered dose spray is ready to prime before use.



2. Gently clear your child's nose.
3. Remove protective cap.
4. Before using for the first time, prime the pump by actuating 4 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be reprimed with 2 actuations. Be very careful not to spray in the eyes or mouth.

5. Hold bottle upright with thumb under base and nozzle between two fingers.



6. Lean your child's head forward slightly and insert the nozzle into the nostril. Spray and ask the child to breathe in gently through the nose at the same time.



7. Repeat with the other nostril.

8. Clean and dry the nozzle before replacing back the cap right after use.

9. To avoid possible spread of infection, the spray should only be used by one person.

Otrivin Adult Nasal Metered-Dose Spray

1. Do not cut the nozzle. The metered-dose spray is ready to prime before use.
2. Before the first application, prime the pump by actuating 4 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be reprimed with 4 actuations. Be very careful not to spray in the eyes or mouth.
3. Hold bottle upright with thumb under base and nozzle between two fingers
4. Clear your nose.

5. Lean forward slightly and insert the nozzle into a nostril.
6. Depress pump and sniff at the same time, so as to ensure optimal distribution of the spray.
7. Repeat for the other nostril.
8. Clean and dry the nozzle before replacing back the cap right after use.
9. To avoid possible spread of infection, the spray should only be used by one person.
10. The dosing spray permits accuracy of dosage and ensures that the solution is well distributed over the surface of the nasal mucosa.

If you take more OTRIVIN than you should

In case of accidental ingestion, tell your doctor or pharmacist immediately.

Pregnancy and breastfeeding

Do not use OTRIVIN during pregnancy. If you are breastfeeding, OTRIVIN should only be used if recommended by your doctor.

Driving and using machines

OTRIVIN has no effect or negligible effect on the ability to drive and use machines.

If you forget to take OTRIVIN

If you miss a dose and you remember within one hour or so of the missed dose, use it right away. However, if you do not remember until later, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

5. POSSIBLE SIDE EFFECTS

OTRIVIN can have side effects, although not everybody gets them. Not all side effects reported for this medicine are included in this leaflet. **Should your general health worsen while taking this medicine, discontinue use and please consult your doctor, pharmacist or other health care professional for advice.**

STOP using **OTRIVIN** and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- Difficulty breathing, speaking or swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised bumps

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), blurred vision, irregular or fast heartbeat.

Frequency of occurrence unknown:

- nose bleeding, taste disturbances, rebound congestion after discontinuation, sleeplessness.
- Visual disturbances

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF OTRIVIN

- OTRIVIN ADULT NASAL DROPS, PAED. NASAL DROPS and PAED. NASAL METERED-DOSE SPRAY: Store at or below 25 °C.
- OTRIVIN ADULT NASAL METERED- DOSE SPRAY:
Store at or below 25 °C.
- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the container. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. If you no longer need your OTRIVIN, take the unused medicine to your pharmacist for safe disposal.

7. PRESENTATION OF OTRIVIN

OTRIVIN PAED. NASAL DROPS (0,5 mg/ml solution):

High Density Polyethylene dropper bottles containing 10 ml.

OTRIVIN PAED. NASAL METERED-DOSE SPRAY (0,5 mg/ml solution):

High Density Polyethylene bottle mounted with a metered-dose pump and a polypropylene nozzle with a protective cap. Content:10 ml.

OTRIVIN ADULT NASAL DROPS (1 mg/ml solution):

High Density Polyethylene dropper bottles containing 10 ml.

OTRIVIN ADULT NASAL METERED-DOSE SPRAY (1 mg/ml solution):

High Density Polyethylene bottle mounted with a metered-dose pump and a polypropylene nozzle with a protective cap. Content:10 ml.

8. IDENTIFICATION OF OTRIVIN

Clear, colourless solution.

9. REGISTRATION NUMBERS

OTRIVIN ADULT NASAL DROPS and OTRIVIN ADULT NASAL METERED-DOSE SPRAY

1 mg/ml: H/16.1/1382

OTRIVIN PAED. NASAL DROPS and OTRIVIN PAED. NASAL METERED-DOSE SPRAY 0,5 mg/ml: H/16.1/1381.

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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