

PACKAGE LEAFLET: INFORMATION FOR THE USER

Otrivin Menthol (without preservative) 1 mg/ml nasal spray, solution Xylometazoline hydrochloride

Read all of this leaflet carefully before you start using this medicine because 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.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Otrivin Menthol is and what it is used for
2. What you need to know before you use Otrivin Menthol
3. How to use Otrivin Menthol
4. Possible side effects
5. How to store Otrivin Menthol
6. Content of the pack and other information

1. What Otrivin Menthol is and what it is used for

Otrivin Menthol is a nasal spray with a decongestant effect. It is used for short-term treatment of nasal congestion in connection with colds.

2. What you need to know before you use Otrivin Menthol

Do not use Otrivin Menthol

- if you are allergic to xylometazoline or any of the other ingredients of this medicine (listed in section 6)
- if you have had your pituitary gland surgically removed or after operations where the membrane of the brain may have been damaged if you have narrow angle glaucoma (increased pressure in eyes)
- 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 since Otrivin Menthol is not suitable for you in these circumstances.

Warnings and precautions

Talk to your doctor or pharmacist before using Otrivin Menthol if:

- you have high blood pressure
- you suffer from a heart disease (e.g. long QT syndrome)
- you have overactive thyroid gland (hyperthyroidism)
- you suffer from diabetes

- you have an enlarged prostate gland (prostatic hypertrophy)
- you have a tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma)
- you are being treated with some antidepressants known as:
 - monoamine oxidase inhibitors (MAOIs) or if you have used them within the previous 2 weeks
 - tri-cyclic or tetra-cyclic antidepressants.

If any of the above apply, do not use Otrivin Menthol before talking to your doctor or pharmacist.

People who are sensitive to medicines with an adrenaline-like effect (such as adrenaline, ephedrine) may have side-effects in the form of sleep disturbances, dizziness, trembling, palpitations or increased blood pressure, and should not therefore use Otrivin Menthol without first consulting a doctor.

Otrivin Menthol should not be used longer than ten days in order to avoid a medically induced nasal congestion, which may lead to physical drug dependency.

Otrivin Menthol is not intended for the use in the eyes or mouth.

Do not exceed the recommended dose, especially in children and in the elderly.

Children

Otrivin Menthol must not be used by children below twelve years of age. **Other medicines and Otrivin Menthol**

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

Treatment with Otrivin Menthol can be affected if the product is used at the same time as tricyclic (e.g. clomipramine, amitriptyline) or tetracyclic (e.g. maprotiline) antidepressants. Treatment with Otrivin Menthol may affect the efficacy of monoamine oxidase inhibitors. This is applicable at concomitant use and when monoamine oxidase inhibitors have been taken during the last two weeks before treatment with Otrivin Menthol. .

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. As a precaution, Otrivin Menthol should not be used by pregnant and breast-feeding women. Otrivin Menthol can be used only on prescription while breast feeding.

Driving and using machines

Otrivin Menthol does not affect the ability to drive or use machines.

3. How to use Otrivin Menthol

Always use Otrivin Menthol exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosing instructions for adults and children over twelve years of age:

One spray in each nostril as required 2-3 times daily. Do not exceed 3 applications daily into each nostril. Use for a maximum of ten days in a row. Each spray of Otrivin Menthol delivers

0.14 ml solution.

It is recommended that the last dose is applied before going to bed. Other dosage as prescribed by your doctor.

If used for more than ten days in a row, Otrivin Menthol can cause nasal congestion.

Instructions for use

Remove the protective plastic cap.

Before the first use

Prime the pump by pumping 5 times. Once primed the pump will normally remain charged throughout regular daily treatment periods

1. Clear your nose.
2. Hold the bottle upright with thumb on the actuation button.
3. For a no dripping effect, stay upright and insert the nozzle into a nostril.
4. Press on the button to spray and breath in gently through the nose at the same time.
Repeat this procedure (steps 2 to 4) in the other nostril.
5. After each use, clean and dry the nozzle.
6. Put the protective cap back on until an audible “click” is heard.



1. Clear nose



2. Thumb on button



3. Insert in nose



4. Press button



5. Clean and dry



6. Replace cap

Should the spray not be 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 re-primed with 2 pumps.

If the full spray is not administered, the dose should not be repeated.

Avoid spraying Otrivin Menthol in or around the eyes

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

If you use more Otrivin Menthol than you should

Swedish blue-box text

If you take too much of any medicine, or if a child has taken the medicine by mistake always contact a doctor, hospital or Giftinformationscentralen (dial 112) for risk assessment and advice.

If you forget to use Otrivin Menthol

Do not take a double dose to make up for a forgotten one.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Otrivin Menthol and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Common (may affect up to 1 in 10 people): Headache, nausea, burning sensation or local irritation in the nose, dry nasal mucosa.

Uncommon (may affect up to 1 in 100 people): Nosebleeds

Not known (cannot be estimated from the available data): Allergic reactions (rash, itching), irregular or fast heartbeat, increased blood pressure, transient blurred vision.

If used more than ten days in a row, Otrivin Menthol can cause nasal congestion.

Reporting of side effects

If you get 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 via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Otrivin Menthol

Keep out of the reach and sight of children.
Do not store above 25°C.

Do not use Otrivin Menthol after the expiry date which is stated on the label after EXP and on the carton after UTG. DAT. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Contents of the pack and other information What Otrivin Menthol contains

- The active substance is xylometazoline hydrochloride 1.0 mg/ml.
- The other ingredients are menthol, cineole, disodium edetate, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sodium chloride, sorbitol, macrogol glycerol hydroxystearate, purified water.

The contents are free from preservatives.

What Otrivin Menthol looks like and contents of the pack

Otrivin Menthol is a clear solution available in a 10 ml HD-polyethylene bottle with a thumb laterally actuated metered-dose spray pump.

Marketing Authorisation Holder

<[To be completed nationally]>

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Manufacturer

<[To be completed nationally]>

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