

Package leaflet: Information for the user

Otrivin Comp 0.5 mg/ml + 0.6 mg/ml nasal spray, solution

Xylometazoline hydrochloride/Ipratropium bromide

[For medicines available only on prescription:]

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

[For medicines available without a prescription:]

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.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

[To be completed nationally]

What is in this leaflet

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

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

Otrivin Comp is a combination medicinal product consisting of two different substances. One of the active ingredients helps against runny nose, the other has a decongesting effect.

Otrivin Comp is used for the treatment of nasal congestion with runny nose (rhinorrhea) in connection with common colds.

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

Do not use Otrivin Comp

- In children below 18 years of age, as adequate information on safety and efficacy is not available
- If you are allergic to xylometazoline hydrochloride or ipratropium bromide or any of the other ingredients of this medicine (listed in section 6)
- If you are allergic to atropine or atropine like substances such as hyoscyamine and scopolamine

- If you had your pituitary gland removed by surgery carried out through the nose
- If you have had brain surgery where the operation was carried out through the nose or mouth
- If you suffer from glaucoma (increased pressure in the eyes)
- If you have a very dry nose (inflammatory nasal dryness, rhinitis sicca or atrophic rhinitis)

Warnings and precautions

Otrivin Comp may give you sleep disturbances, dizziness, tremor, irregular heart rhythm or elevated blood pressure in case you are sensitive to medicines for the relief of blocked nose. Consult your doctor if these symptoms occur and are bothersome.

Talk to your doctor or pharmacist before using Otrivin Comp if you suffer from:

- Heart disease (e.g. long QT syndrome)
- Raised blood pressure
- Diabetes
- An overactive thyroid gland (hyperthyroidism)
- Difficulty in urinating and/or an enlarged prostate gland
- Narrow-angle glaucoma
- A tendency to have nosebleeds
- Obstruction of the intestine (paralytic ileus).
- Cystic fibrosis
- Benign tumour of the adrenal gland that produces high amounts of adrenaline and nor-adrenaline (phaeochromocytoma) or a particular sensitivity to adrenaline and nor-adrenaline

Immediate hypersensitivity (allergic reaction) may occur. This may be seen as itchy red rash with raised inflammation of the skin (hives), difficulty breathing or speaking, difficulty swallowing due to swelling of the lips, face or throat. These symptoms may appear individually or all combined as a severe allergic reaction. If this occurs, immediately STOP using Otrivin Comp (see section 4).

Otrivin Comp should not be used for more than 7 consecutive days. If symptoms persist, consult a doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen and swelling of the nasal mucosa.

Avoid spraying Otrivin Comp in or around the eyes. If this happens thoroughly rinse the eyes with cold water. Your vision may become temporarily blurred and the eye irritated, painful and red. If this happens contact your doctor for advice. Worsening of narrow angle glaucoma may also occur.

Children and adolescents

Otrivin Comp is not recommended for use in children and adolescents below 18 years of age as adequate information on safety and efficacy is not available.

Other medicines and Otrivin Comp

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is particularly important that you mention the following:

- Monoamine oxidase inhibitors (used for treatment of depression). If you are taking or have taken these medicines in the last two weeks, dangerous rises of the blood pressure may occur
- Tri-cyclic and tetra-cyclic antidepressants. If you are taking or have taken these medicines in the last two weeks, dangerous rises of the blood pressure may occur
- Medicines used for travel sickness (medicines containing anticholinergic substances)
- Medicines used for gut disorders (particularly those for abnormal motility) (medicines containing anticholinergic substances)

- Medicines used for the treatment of breathing disorders (Beta 2-agonists) such as asthma or chronic obstructive pulmonary disease (COPD) as it may worsen your glaucoma if you have a history of angle closure glaucoma.

If you use any of the above medicines, consult a doctor before using Otrivin Comp.

Pregnancy and breast-feeding

Otrivin Comp should not be used during pregnancy unless your doctor recommends it. During breast-feeding, Otrivin Comp should not be used unless your doctor decides the advantages outweigh the potential risks to the infant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

Visual disturbances (including blurred vision and dilation of the pupil), dizziness and fatigue have been reported with Otrivin Comp. If affected, you should avoid driving, operating machinery or taking part in activities where these symptoms may put yourself or others at risk.

3. How to use Otrivin Comp

[For medicines available on prescription only:]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without a prescription:]

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

The recommended dose is:

Adults: One puff in each nostril as needed, up to 3 times daily for maximum 7 days. Leave at least 6 hours between two doses. Do not exceed 3 applications daily into each nostril.

Do not exceed the stated dose. Use the smallest dose you need to treat your symptoms and use it for the shortest time needed to achieve desired effect.

Duration of treatment:

Do not use this medicine for more than 7 days.

It is recommended that you stop treatment with Otrivin Comp as soon as your symptoms improve even if this is sooner than 7 days, in order to minimize the risk of adverse reactions.

If symptoms get worse or do not improve after 7 days, consult a doctor. **[To be completed nationally]**

If you think the effect of Otrivin Comp is too strong or too weak, consult your doctor or pharmacist.

Instructions for use:

- Remove the dust cap
- Do not cut the nozzle. The metered dose spray is ready to prime before use



- Before the first application, prime the pump by pumping 4 times. Once primed the pump will normally remain charged throughout regular daily treatment periods. Should the spray not be ejected during the full actuation stroke, or if the product has not been used for longer than 6 days, the pump will need to be re-primed with 4 pumps as initially performed

1. Clear your nose.
2. Hold the bottle upright with thumb under base and nozzle between two fingers.
3. Lean forward slightly and insert the nozzle into a nostril.
4. Press the pump to spray and breath in gently through the nose at the same time.
5. Repeat this procedure (steps 1 to 4) in the other nostril.
6. Clean and dry the nozzle before replacing back the cap right after use.

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

Avoid spraying Otrivin Comp in or around the eyes.

The effect occurs within 5-15 minutes.

If you use more Otrivin Comp than you should:

If you, or someone else, have taken more medicine than you should, contact your doctor, hospital or emergency room for assessment of the risk. It is advisable to take this leaflet, bottle or pack with you. This is particularly important for children who are more likely to develop adverse events than adults. Symptoms of overdose are severe dizziness, sweating, severely lowered body temperature, headache, slow heartbeat, rapid heartbeat, impaired breathing, coma, convulsion, hypertension (high blood pressure) which may be followed by hypotension (low blood pressure). Other symptoms may be dry mouth, difficulties focusing with the eye and hallucinations.

[If Poison Information Centre exists in local market and supports consumer enquiries include details below:]

Poison Information Centre (include contact details: Phone + Website + Email).

If you forget to use Otrivin Comp

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

4. Possible side effects

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

STOP using Otrivin Comp and seek medical help immediately if you have any of the following:

- Palpitations and increased heart rate (affects less than 1 in 100 people)
- Signs of an allergic reaction as 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 (frequency not known cannot be estimated from available data)
- Disturbances of vision (including blurred vision, worsening of glaucoma or increased pressure in the eye), rainbow-coloured circles/haloes around bright lights and/or eye pain (frequency not known cannot be estimated from available data)

The most common side effects are nose bleeding and nasal dryness. Many of the side effects reported are also symptoms of common cold.

Very common side effects (may affect more than 1 in 10 people):

- Nose bleeding

Common side effects (may affect up to 1 in 10 people):

- Nasal discomfort, congestion of the nose, dry nose, pain in the nose
- Dry mouth, dry or irritated throat

- Altered taste sensation, headache, dizziness, local burning sensation
- Nausea

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

- Nasal ulcer, sneezing, pain in the throat, cough, hoarseness
- Stomach upsets
- Altered smell sensation, shakiness
- Discomfort, tiredness
- Sleeplessness
- Irritation of the eyes, dry eyes, swelling of the eyes, redness of the eyes
- Palpitations, increased heart rate

Rare (may affect up to 1 in 1,000 people):

- Runny nose

Very rare (may affect up to 1 in 10,000 people):

- Reaction to the medicine such as swelling, rash, itching
- Visual impairment

Frequency not known (cannot be estimated from available data):

- Hives
- Discomfort around the nose
- Difficulty swallowing
- Discomfort in the chest, thirst
- Sudden spasm of throat muscle, swelling of throat
- Irregular heart rhythm
- Difficulties focusing with the eyes, dilation of the pupils, flashing lights, increased eye pressure, glaucoma, blurred vision, haloes around bright lights and eye pain
- Difficulties emptying the bladder

In order to minimise the risk of side effects, it is recommended that you stop treatment with Otrivin Comp as soon as your symptoms improve.

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 listed in Appendix V](#) (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Country name [To be completed nationally]

{Name}

<{Address}

{Town} {Postal code} – Country>

Tel: + {Telephone number}

<website>

5. How to store Otrivin Comp

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. This date applies even if the packaging has been opened.

Do not store above 25°C.

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 protect the environment.

6. Contents of the pack and other information

What Otrivin Comp contains

The active substances are xylometazoline hydrochloride and ipratropium bromide.

1 ml contains 0.5 mg xylometazoline hydrochloride and 0.6 mg ipratropium bromide.

1 puff contains 70 micrograms xylometazoline hydrochloride and 84 micrograms ipratropium bromide.

The other ingredients are disodium edetate, glycerol (85 %), purified water, sodium hydroxide and hydrochloric acid.

What Otrivin Comp looks like and contents of the pack

Otrivin Comp is a clear solution.

The bottle contains approximately 70 puffs.

Otrivin Comp is available as a 10 ml nasal spray with a metered-dose spray pump.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

{Name and address }

<{tel}>

<{fax}>

<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:

| | |
|----|---|
| AT | Otrivin Duo 0,5 mg/ml + 0,6 mg/ml Nasenspray, Lösung |
| BE | Otrivine Duo 0,5mg/ml + 0,6mg/ml solution pour pulvérisation nasale |
| CY | Otrivin Advance (0,5mg/ml + 0,6mg/ml) nasal spray solution |
| CZ | Otrivin Rhinostop |
| DK | Otrivin Comp næsespray, opløsning |
| EE | Otrinex, 0,5 mg/0,6 mg/ml ninasprei, lahus |
| EL | Otrivin Advance 0,5mg/ml + 0,6mg/ml Ρινικό εκνέφωμα, διάλυμα |
| ES | Rhinovín Duo 0,5 mg/ml + 0,6 mg/ml solución para pulverización nasal |
| FI | Otrivin Comp 0,5mg/ml + 0,6mg/ml nenäsumute, liuos |
| HU | Otrivin Komplex 0,5mg/ml + 0,6 mg/ml oldatos orrspray |
| IE | Otrivine Extra Dual Relief 0.5mg/ml + 0.6mg/ml Nasal Spray |
| IS | Otrivin Comp 0,5mg/ml + 0,6mg/ml nefúði lausn |
| IT | RINAZINA DOPPIA AZIONE 0,5 mg/ml + 0,6 mg/ml spray nasale, soluzione |
| LT | Otrinex 0,5 mg/0,6 mg/ml nosies purškalas (tirpalas) |
| LU | Otrivine Duo 0,5mg/ml + 0,6mg/ml solution pour pulvérisation nasale |
| LV | Otrinex 0,5 mg/0,6 mg/ml deguna aerosols, šķīdums |
| MT | Otrivine Extra Dual Relief 0.5mg/ml + 0.6mg/ml Nasal Spray |
| NL | Otrivin Duo Xylometazoline hydrochloride & Ipratropium bromide, 0,5/0,6 mg/ml, neusspray, oplossing |
| NO | Otrivin Comp 0,5mg/ml + 0,6mg/ml neseppray, oppløsning |
| PL | Otrivin Ipra MAX |
| PT | Vibrocil ActilongDuo 0.5mg/ml + 0.6mg/ml solução para pulverização nasal |
| RO | Vibrocil Duo 0,5mg/ml + 0,6mg/ml spray nazal, solutie |

SE Otrivin Comp 0,5mg/ml + 0,6 mg/ml nässpray lösning
SI Otrivin Duo 0,5 mg/0,6 mg v 1 ml pršilo za nos, raztopina

This leaflet was last revised: 2023-04-22