

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

Otrivin Complete 0.05% w/v + 0.06% w/v

Metered Dose Nasal Spray

Ipratropium Bromide 0.06% w/v
Xylometazoline Hydrochloride 0.05% w/v

Inactive ingredients and allergens in the medicine – see section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

Use the medicine according to the instructions in the section “How should you use the medicine?” in this leaflet. Consult the pharmacist if you need more information.

Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.

1. What is the medicine intended for?

Treatment of symptoms of nasal congestion and rhinitis associated with the common cold in adults.

Therapeutic class:

Ipratropium bromide, an anticholinergic agent, which helps in case of rhinitis.

Xylometazoline hydrochloride, a sympathomimetic agent, which has a decongesting effect.

2. Before using the medicine

Do not use the medicine if:

- You are a child or are treating a child under the age of 18, as no information is available regarding its safety and efficacy.
- You are sensitive (allergic) to the active ingredients (ipratropium bromide, xylometazoline hydrochloride) or to any of the other components the medicine contains (see section 6).
- There is a known sensitivity to atropine or to similar agents, such as hyoscyamine and scopolamine.
- You have undergone surgery in which the hard external membrane in the central nervous system (dura mater) was penetrated, e.g., surgery to remove your pituitary gland (hypophysis) through the nose, or other surgery carried out through the nose.
- You have glaucoma (increased pressure in the eye).
- You have a very dry nose (inflammatory nasal dryness, rhinitis sicca or atrophic rhinitis).

Special warnings regarding the use of the medicine

Before treatment with Otrivin Complete, inform the doctor or the pharmacist if you have:

- Heart disease (e.g., long QT syndrome).
- High blood pressure.
- Diabetes.
- An overactive thyroid (hyperthyroidism).
- Difficulty urinating and/or enlarged prostate.
- Narrow-angle glaucoma (a sharp increase in intra-ocular pressure).
- A tendency to have nosebleeds.
- A bowel obstruction (small intestine).
- Cystic fibrosis.
- A benign tumor in the adrenal glands, which secretes large amounts of adrenaline and noradrenaline (pheochromocytoma) or if you are particularly sensitive to adrenaline and noradrenaline.

Otrivin Complete may cause sleep disturbances, dizziness, tremor, irregular heart rate or elevated blood pressure in very sensitive patients. Consult with the doctor if these effects occur and bother you.

Immediate hypersensitivity (an allergic reaction) may occur in rare cases. The symptoms may include: an itchy red rash with blisters, difficulty breathing or speaking, difficulty swallowing due to swelling of the lips, face or throat. These symptoms may appear individually or together as a severe allergic reaction. If this occurs, you should **immediately stop** using Otrivin Complete (see section 4 - "Side effects").

Prolonged or excessive use may cause recurring or worsening sense of stuffiness in the nose and swelling of the nasal mucosa.

Children, adolescents and the elderly

Use of Otrivin Complete is not recommended for children and adolescents under the age of 18, due to insufficient information regarding safety and efficacy. The use in elderly people over the age of 70 is not recommended, due to insufficient information regarding safety and efficacy.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Monoamine oxidase inhibitors (MAOIs) for treatment of depression. If you are taking or have taken these in the last two weeks, a dangerous elevation of blood pressure may occur.
- Tricyclic or tetracyclic antidepressants. If you are taking or have taken these in the last two weeks, a dangerous elevation of blood pressure may occur.

- Medicines for treatment of motion sickness (medicines containing anticholinergic agents).
- Medicines used for bowel disorders, particularly for abnormal motility (medicines containing anticholinergic agents).
- Medicines used for treatment of breathing disorders (beta 2-agonists) such as asthma or chronic obstructive pulmonary disease (COPD), as this may worsen glaucoma if there is a history of narrow-angle glaucoma.

If you use any of the abovementioned medicines, consult the doctor before using Otrivin Complete.

Pregnancy and breastfeeding

Do not use Otrivin Complete during pregnancy unless your doctor recommends it. Do not use Otrivin Complete during breastfeeding, unless your doctor thinks the benefit outweighs the potential risks to the child.

If you are pregnant, think you might be pregnant, are planning to become pregnant or breastfeeding, you should consult the doctor or pharmacist before using the medicine.

Driving and operating machinery

Visual disturbances (including blurry vision and dilated pupils), dizziness and fatigue have been reported during use of Otrivin Complete. If you are affected by the above, avoid driving, operating machinery or taking part in activities that may put yourself and others at risk.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

Adults above 18 years of age: one puff in each nostril, up to 3 times in 24 hours.

You should wait at least 6 hours between doses.

Do not exceed the recommended dose.

Use the lowest dosage that enables treatment of the symptoms and for the shortest possible time to achieve the desired effect.

Do not use the medicine for more than 7 days. Using the medicine for more than 7 days may cause the nasal mucosa to swell.

Duration of treatment:

Do not use this preparation for more than 7 days.

It is recommended to stop using Otrivin Complete as soon as the symptoms improve, even if less than 7 days have passed from the beginning of the treatment, in order to minimize the risk of side effects.

If you think that the effect of the medicine is too weak or too strong, consult the doctor or the pharmacist.

Do not swallow.

Method of use:

- Remove the protective cap.
- Do not cut the nozzle. The metered dose spray is ready for use.



- Before the first use, prime the pump by pumping 4 times. Once primed, the pump will usually remain charged throughout the period of daily treatment. If the spray is not ejected following full actuation of the pump, or if the medicine has not been used for longer than 6 days, the pump will need to be reprimed. Press the pump 4 times as initially performed.
 1. Blow your nose.
 2. Hold the bottle in an upright position with the thumb under its base and the nozzle between your two fingers.
 3. Lean forward slightly and insert the nozzle into the nostril.
 4. Press the pump while inhaling gently through the nose.
 5. Repeat this procedure (steps 1-4) in the other nostril.
 6. Clean and dry the nozzle before replacing the protective cap immediately after use.

To prevent the spread of infection, this package is intended to be used by one person only.

The effect of the medicine will be noticed 5-15 minutes after use.

Avoid spraying Otrivin Complete in or around the eyes. If this happens, wash your eyes thoroughly with cold water. Your vision may be temporarily blurry. Irritation, redness and pain in the eyes may occur. Contact the doctor if this happens. Narrow-angle glaucoma may worsen.

If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. It is particularly important in children, since they have a greater tendency to develop side effects.

Symptoms of an overdose include severe dizziness, sweating, severe lowering of body temperature, headache, slowing of the heart rate or accelerated heart rate, difficulty breathing, coma, convulsions, a rise in blood pressure which may be followed by a drop in blood pressure.

Other symptoms may be dry mouth, difficulty focusing the eyes and hallucinations.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

- **Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

4. Side effects

As with any medicine, using Otrivin Complete may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using this medicine and refer to a doctor immediately if you experience any of the following symptoms:

- Palpitations and increased heart rate (affects less than 1 in 100 users).
- Signs of an allergic reaction, such as difficulty breathing, speaking or swallowing; swelling of the face, lips, tongue or throat; severe itching with a red rash and raised bumps (unknown frequency, cannot be estimated from the available data).
- Visual disturbances (blurry vision, worsening of glaucoma or increased pressure in the eye), rainbow-colored circles or haloes around bright lights and/or eye pain (unknown frequency, cannot be estimated from the available data).

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

Very common side effects – effects that occur in more than one out of ten users

- Nose bleeding.

Common side effects – effects that occur in 1-10 users out of 100

- Nasal discomfort, nasal congestion, nasal dryness, pain in the nose.
- Dry mouth, dry and irritated throat.
- Altered sense of taste, headache, dizziness, a localized feeling of burning.
- Nausea.

Uncommon side effects – effects that occur in 1-10 users out of 1,000

- Nasal ulcer, sneezing, sore throat, cough, hoarseness.
- Stomach irritation.
- Altered sense of smell, tremor.
- Discomfort, tiredness.
- Insomnia.
- Eye irritation, dry eyes, eye swelling, redness in the eyes.
- Palpitations, accelerated heart rate.

Rare side effects – effects that occur in 1-10 users out of 10,000

- Rhinitis.

Very rare side effects – effects that occur in less than one user out of 10,000

- Reaction to the medicine, such as swelling, rash, itch.
- Visual disorders.

Side effects with unknown frequency (effects whose frequency has not yet been determined)

- Hives.
- Discomfort around the nose.
- Difficulty swallowing, sudden spasm of the throat muscles, swelling of the throat.
- discomfort in the chest, thirst.

- Irregular pulse.
- Difficulty focusing the eyes, dilated pupils, flashes of light, increased ocular pressure, glaucoma, blurry vision, a halo around bright lights and eye pain.
- Problems with emptying the bladder.

To minimize the risk of side effects, it is recommended that you stop treatment with Otrivin Complete when your symptoms improve.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C.

After opening the bottle for the first time, the medicine can be used up to the expiry date appearing on the package.

6. Additional information

- **In addition to the active ingredients the medicine also contains:**
Glycerol (85 percent), Disodium edetate, Hydrochloric acid concentrated, Sodium hydroxide, Purified water.
- **What does the medicine look like and what are the contents of the package?**
Otrivin Complete is a colorless or slightly colored clear solution, packed in a 10 ml bottle (metered spray pump and a protective cap).
- **License holder and address:**
Haleon CH Israel Ltd., P.O.box 3256, Petach Tikva.
- **Name and address of the manufacturer:**
Haleon CH SARL, Route de l'Etraz 1260, Nyon, Switzerland.
- **Registration number of the medicine in the national drug registry of the Ministry of Health:** 147-78-33385

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