

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

This medicine is dispensed without a doctor's prescription

## **Otrivin Complete 0.5 mg/ml + 0.6 mg/ml**

### **Nasal Metered Dose Spray**

Ipratropium Bromide 0.6 mg/ml  
Xylometazoline Hydrochloride 0.5 mg/ml

Inactive and allergenic ingredients 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 any other questions, refer to the doctor or the pharmacist.

Use the medicine according to the instructions in the dosage section of 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 runny nose associated with the common cold.

#### **Therapeutic class:**

Ipratropium bromide, an anticholinergic agent, which helps to treat runny nose.  
Xylometazoline hydrochloride, a sympathomimetic agent, which has a decongesting effect.

### **2. Before using the medicine**

#### **Do not use this medicine if:**

- Do not use the medicine in children 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 had your pituitary gland (hypophysis) removed by surgery carried out through the nose.
- You had brain surgery carried out through the nose or the mouth.
- You have glaucoma (increased pressure in the eye).
- You have a very dry nose (inflammatory nasal dryness, rhinitis sicca).

#### **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 for 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, since you may experience dizziness, tremor, palpitations, hypertension and insomnia.

Immediate hypersensitivity (an allergic reaction) may occur in rare cases. The symptoms may include: an itchy red rash with blisters (urticaria), difficulty breathing and 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, you should **immediately** stop using Otrivin Complete (see section 4 - "Side effects").

Narrow-angle glaucoma may worsen.

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

Using the medicine in elderly people over the age of 70 is not recommended, due to insufficient information regarding safety and efficacy.

### **Children and adolescents**

Use of Otrivin Complete is not recommended for children and adolescents under the age of 18, 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 food supplements, tell the doctor or the pharmacist.** Especially if you are taking:

- Monoamine oxidase inhibitors (MAO inhibitors) 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).
- Medicines for treatment of motion sickness (medicines containing anticholinergic agents).
- Medicines used for bowel disorders (particularly for abnormal motility) (medicines containing anticholinergic agents).

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 infant.

If you are pregnant, think you might be pregnant, 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 experience the above effects, you should 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 medicine.

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 use the medicine for more than 7 days. Using the medicine for more than 7 days may cause the nasal mucosa to swell up.

Experience with the medicine is very limited in patients above 70 years of age.

**Do not exceed the recommended dose.**

#### **Duration of treatment:**

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 for 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:

- Always blow your nose before using the nasal spray.
- Remove the protective cap.
- Do not cut the nozzle. The metered dose spray is ready for use.



- Before the first application, prime the pump by pumping 4 times. Once primed, the pump will normally remain charged throughout the period of regular 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.
- Hold the bottle upright.
- Bend your head slightly forward.
- Close one nostril by placing your finger against the side of your nose, and insert the spray tip into the other nostril. Press the pump quickly while inhaling through the nose.
- Repeat this procedure in the other nostril.

You will notice the effect of the medicine after 5-15 minutes.

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.

**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 overdose include severe dizziness, sweating, severely lowered body temperature, headache, slow heartbeat or rapid heartbeat, impaired 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.

- 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 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 one 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 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 available data).

The most 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 (side effects that occur in more than one out of ten users)

- Nose bleeding, nasal dryness.

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

- Nasal discomfort, nasal congestion, dry and irritated throat, pain in the nose.
- Dry mouth.
- Altered taste sensation, headache.

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

- Nasal ulcer, sneezing, sore throat, cough, hoarseness.
- Stomach irritation, nausea.
- Altered smell sensation, dizziness, tremor.
- Discomfort, tiredness.
- Insomnia.
- Eye irritation, dry eyes.

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

- Rhinitis.

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

- Rash, hives.
- Discomfort around the nose.
- Discomfort in the chest, thirst.
- Sudden spasm of the throat muscles.
- Irregular pulse.
- Difficulty focusing the eyes, dilation of the pupils.
- Itching.
- Problems in bladder emptying.

To minimize the risk of side effects such as nose bleeding or other effects on the nose, it is recommended that you stop treatment with Otrivin Complete when your symptoms improve, even if this happens sooner than 7 days.

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](http://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/label. The expiry date refers to the last day of that month.

Store at a temperature lower than 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:  
Purified water, Glycerol (85 percent), Disodium edetate dihydrate, Hydrochloric acid concentrated, Sodium hydroxide (for pH adjustment).
- 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 cover).
- **License holder and address:**  
GSK Consumer Healthcare Israel Ltd., P.O. Box 3256, Petah Tikva
- **Name and address of the manufacturer:**  
GSK Consumer Healthcare S.A., Nyon, Switzerland
- Registration number of the medicine in the national drug registry of the Ministry of Health: 147-78-33385

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