OTRIVIN PLUS NASAL SPRAY

Active ingredient: Xylometazoline hydrochloride 70 micrograms/spray; Ipratropium bromide 84 micrograms/spray

This leaflet provides important information about using Otrivin Plus Nasal Spray. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Otrivin Plus Nasal Spray.

Where to find information in this leaflet:

- 1. Why am I using Otrivin Plus Nasal Spray?
- 2. What should I know before I use Otrivin Plus Nasal Spray?
- 3. What if I am taking other medicines?
- 4. How do I use Otrivin Plus Nasal Spray?
- 5. What should I know while using Otrivin Plus Nasal Spray?
- 6. Are there any side effects?
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1. Why am I using Otrivin Plus Nasal Spray?

Otrivin Plus Nasal Spray contains the active ingredients Xylometazoline hydrochloride & Ipratropium bromide.

Otrivin Plus Nasal Spray is used for the relief of blocked and runny nose caused by colds, hay fever or other allergic rhinitis. It is indicated in adults 18 years and over.

2. What should I know before I use Otrivin Plus Nasal Spray?

Warnings

Do not use Otrivin Plus Nasal Spray:

- in children and adolescents below 18 years of age.
- if you are allergic to xylometazoline, ipratropium or any other ingredients of this medicine. Always check the ingredients to make sure you can use this medicine.
- if you are allergic to atropine or similar substances such as hyoscyamine and scopolamine.
- if you have had the pituitary gland removed by operation through the nose.
- 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 because Otrivin Plus Nasal Spray is not suitable for you in these circumstances.

Frequent or prolonged use may cause nasal congestion to recur or worsen.

Otrivin Plus Nasal Spray is for nasal use only. Brief stinging sensation or sneezing may occur. Excessive use may damage lining of nose.

Check with your doctor or pharmacist if you:

- have any other medical conditions [high blood pressure; heart disease (e.g. long QT syndrome); an overactive thyroid gland (hyperthyroidism); diabetes; difficulty in urinating and/or an enlarged prostate gland (prostatic hypertrophy); the tendency to have nose bleeds; have a rare tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma), suffer from cystic fibrosis, the tendency to suffer from blockage of the intestine (paralytic ileus)].
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant. Do not use Otrivin Plus Nasal Spray if you are pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. Otrivin Plus Nasal Spray should only be used if recommended by your doctor.

Children and adolescents

 Do not use Otrivin Plus Nasal Spray in children and adolescents below 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Otrivin Plus Nasal Spray and affect how it works.

It is particularly important to mention to your doctor or pharmacist if you are taking or have taken the following medicines:

- certain medicines used for the treatment of breathing disorders such as asthma or chronic obstructive pulmonary disease (COPD)
- Monoamine oxidase (MAO) inhibitors (used for treatment of depression): Otrivin Plus Nasal Spray is not recommended if you are taking or have been taking these medicines within the last 14 days. Use with Otrivin Plus Nasal Spray may substantially increase blood pressure.
- Tri-cyclic and tetra-cyclic antidepressants: use with Otrivin Plus Nasal Spray may increase the effects of xylometazoline (an active ingredient in Otrivin Plus Nasal Spray).

Otrivin Plus may also increase the effect of medicines containing anticholinergic substances used for gut disorders (particularly for reducing intestinal motility) and motion sickness.

If you use any of the above-mentioned medicines, consult a doctor before using Otrivin Plus Nasal Spray.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Otrivin Plus Nasal Spray.

4. How do I use Otrivin Plus Nasal Spray?

How much to use

- Always use Otrivin Plus Nasal Spray exactly as recommended below. You should check with your doctor or pharmacist if you are not sure.
- Adults 18 years and over: 1 spray into each nostril as needed up to 3 times daily. Do not exceed 3 sprays into each nostril daily. Do not use more often than every 6 hours.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage, especially in children and the elderly.
- Use the smallest dose you need to treat your symptoms and use it for the shortest time needed to achieve desired effect.
- If you forget to use Otrivin Plus Nasal Spray do not take a double dose to make up for a forgotten one.

When to use Otrivin Plus Nasal Spray

 Otrivin Plus Nasal Spray should be used when necessary. Do not exceed 3 applications daily in each nostril. Do not use more often than every 6 hours.

How to use Otrivin Plus Nasal Spray

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



- 2. Clear your nose.
- 3. Remove protective cap.
- 4. Before using for the first time, prime the pump by pumping 4 times. Once primed, the pump will normally remain charged throughout the 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 7 days, the pump will need to be reprimed with 4 pumps as initially performed. 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 forward slightly and insert the nozzle into the nostril. Spray and 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 capright after use.
- 9. To avoid possible spread of infection, the spray should only be used by one person.

If you use too much Otrivin Plus Nasal Spray

Signs of an overdose may include 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 you think that you have used too much Otrivin Plus Nasal Spray, or in case of accidental ingestion, you should seek urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (telephone: Australia 13 11 26; New Zealand 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Otrivin Plus Nasal Spray?

Things you should do

If congestion persists, seek medical advice.

Each pack should be used by only one person, for reasons of hygiene.

If irritation occurs or you have signs of allergy, discontinue

If you accidently spray into your eyes, rinse the eyes thoroughly with running water and contact your doctor immediately for advice as to what treatment is needed. You may experience temporary blurring of vision, irritation of the eye, painful or red eyes. Worsening of narrow-angle glaucoma may also occur.

Remind any doctor, dentist or pharmacist you visit that you are using Otrivin Plus Nasal Spray.

Things you should not do

- Otrivin Plus Nasal Spray is not intended for use in the eyes or mouth.
- Do not use in or around the eyes.
- Do not use for more than 3 days at a time unless advised by a doctor or pharmacist. If congestion persists, seek medical advice.

Product tampering

 Otrivin Plus Nasal Spray is enclosed in a tamperevident carton to help protect you from product tampering. If you find that the carton seals have been broken or are missing, do not use the product and return it to the place of purchase.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Otrivin Plus Nasal Spray affects you.

If you experience problems with vision, dizziness or fatigue while taking Otrivin Plus Nasal Spray, you should not drive, operate machinery or take part in activities where these symptoms may put yourself or others at risk.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

- Store below 25°C.
- Keep out of reach and sight of children.
- Do not use Otrivin Plus Nasal Spray after the expiry date which is stated on the outer pack and on the immediate container. The expiry date refers to the last day of that month.
- Store in the original package.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not throw away your medicine in your household waste.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Like other products for the relief of blocked nose, Otrivin Plus Nasal Spray may give rise to sleep disturbances,

dizziness, tremor, an irregular heartbeat or high blood pressure in very sensitive patients. Consult your doctor if such signs prove troublesome. If any of the above apply, do not use Otrivin Plus Nasal Spray before talking to your doctor or pharmacist.

Stop using Otrivin Plus Nasal Spray and seek immediate medical attention if you experience sudden severe headaches, nausea and vomiting, or visual disturbances. These symptoms may be associated with a rare but serious side effect.

See the information below. Stop taking Otrivin Plus Nasal Spray and tell your doctor immediately if you experience:

Common side effects

Common side effects		What to do
•	Dryness or irritation of the nose Stuffiness or discomfort or pain in the nose Nosebleed Dry mouth Dry or irritated throat Altered sense of taste Nausea Abdominal intestinal contractions Headache Dizziness Local burning sensation	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Very rare side effects

Very rare side effects	What to do
Nervous system disorders: Allergic reactions (difficulty breathing or swallowing, swelling of the face, lips, tongue or throat) Blurred vision Irregular or fast heartbeat	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or to the Centre for Adverse Reactions Monitoring at https://pophealth.my.site.com/carmreportnz/s/ in New

Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Otrivin Plus Nasal Spray contains

Active ingredients (main ingredients)	Xylometazoline hydrochloride 70 micrograms/spray Ipratropium bromide 84 micrograms/spray
Other ingredients	Glycerol
(inactive ingredients)	Disodium edetate
	Hydrochloric acid
	Purified water

Do not take this medicine if you are allergic to any of these ingredients.

What Otrivin Plus Nasal Spray looks like

Otrivin Plus Nasal Spray is a clear, colourless to slightly coloured solution in a metered-dose spray container.

Who distributes Otrivin Plus Nasal Spray

Haleon

Sydney, NSW, Australia & Auckland, New Zealand

AU: 1800 028 533 NZ: 0800 540 144

This leaflet was prepared in February 2024.