

## New Zealand Consumer Medicine Information

### **ATROVENT<sup>®</sup> Nasal Aqueous Spray**

*Ipratropium bromide Solution 0.03% w/v*

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#### **What is in this leaflet**

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This leaflet answers some common questions about ATROVENT Nasal Aqueous 0.03% spray solution. It does not contain all available information. It does not take the place of talking to your doctor or pharmacist. Keep this information with your nasal spray. You may need to read it again later.

#### ***To find out more about ATROVENT Nasal Aqueous***

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using ATROVENT Nasal Aqueous.

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#### **What ATROVENT Nasal Aqueous is used for**

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ATROVENT Nasal Aqueous relieves the symptoms of a persistent runny nose. A runny nose is a typical symptom of the condition known as rhinitis. Rhinitis may be caused by allergies, the common cold, or other stimuli such as temperature changes or food.

ATROVENT Nasal Aqueous relieves a runny nose by acting directly on the mucous glands of the nose to decrease watery secretions.

ATROVENT Nasal Aqueous is known as an anticholinergic medicine. It belongs to one of several types of medicines used to treat the symptoms of rhinitis.

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#### **Before you use ATROVENT Nasal Aqueous**

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##### ***When not to use ATROVENT Nasal Aqueous***

Do not use ATROVENT Nasal Aqueous if you are allergic to it or to any of the ingredients. These ingredients are listed in full at the end of this leaflet.

In some cases you should not use ATROVENT Nasal Aqueous if you are allergic to certain other medicines. You must tell your doctor or pharmacist if you are allergic to any other medicine, particularly atropine or other anticholinergic medicines. If you are uncertain as to whether you have these allergies you should raise those concerns with your doctor or pharmacist.

You should not use ATROVENT Nasal Aqueous if the packaging is torn or shows signs of tampering. You should never use ATROVENT Nasal Aqueous after the EXPIRY DATE on the bottle or carton. If you use it after the expiry date has passed, it may not work as well.

##### ***Before you start to use ATROVENT Nasal Aqueous***

Before using ATROVENT Nasal Aqueous, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- an eye problem called "glaucoma"
- enlargement of the prostate gland
- problems with passing urine
- cystic fibrosis.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor or pharmacist.

ATROVENT Nasal Aqueous contains the (antimicrobial) preservative benzalkonium chloride which may cause irritation of the nasal lining (mucosa).

Before using ATROVENT Nasal Aqueous it is advisable to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription, including medicines you buy from a pharmacy, supermarket or health food shop.

In particular, you should tell your doctor if you are taking any other medicine containing ipratropium bromide or another anticholinergic agent such as atropine, hyoscine or hyoscyamine.

### ***Pregnancy***

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. Care is recommended during pregnancy, particularly in the first three months. The benefits of ATROVENT Nasal Aqueous must be assessed against any risks. Your doctor will discuss the risks and benefits of using ATROVENT Nasal Aqueous while you are pregnant.

### ***Breastfeeding***

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. Care is recommended if you are breastfeeding as it is not known if the active ingredient in ATROVENT Nasal Aqueous may pass into breast milk. The benefits of ATROVENT Nasal Aqueous must be assessed against any risks. Your doctor will discuss the risks and benefits of using ATROVENT Nasal Aqueous while you are breastfeeding.

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## **Using ATROVENT Nasal Aqueous**

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### ***How to use ATROVENT Nasal Aqueous***

At the end of this leaflet you will find directions on how to use ATROVENT Nasal Aqueous. Ask your doctor or pharmacist for advice if you have any problems with using this medicine.

Never spray ATROVENT Nasal Aqueous in or around your eyes. If you accidentally spray ATROVENT Nasal Aqueous into your eyes, you may have temporary blurring of vision and increased sensitivity to light, lasting up to a few hours. Contact your doctor immediately for advice as to what treatment is needed.

### ***Recommended Dose***

Relief of allergic or non-allergic rhinitis.

Adults: 2 sprays into each nostril two or three times a day (at regular intervals).

Children: 2 sprays into each nostril two times a day.

Patients who have a runny nose triggered by factors such as temperature changes, food or exercise should use 2 to 4 sprays into each nostril before exposure.

Relief of rhinitis associated with the common cold:

Adults: 2 sprays into each nostril followed by 2 further sprays five minutes later, three or four times a day.

If your doctor or pharmacist has changed this dose you should ask for further information from your doctor or pharmacist.

Do not take extra doses of ATROVENT Nasal Aqueous without consulting your doctor or pharmacist.

### ***If you forget to take a dose***

It is important to use ATROVENT Nasal Aqueous as directed. If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time.

### ***Overdose***

Seek medical advice if you have used more than the recommended or prescribed dose of ATROVENT Nasal Aqueous. Advice can be provided by a doctor, pharmacist or the Poisons Information Centre (telephone 0800 764766). Signs of overdose may include increased heart rate, dry mouth, and blurred vision.

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## **While using ATROVENT Nasal Aqueous**

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### ***Things you must do***

Contact your doctor immediately if you experience eye pain or discomfort, or any disturbances with your sight (blurred vision, visual halos or coloured images) during or after using ATROVENT Nasal Aqueous.

If the spray from ATROVENT Nasal Aqueous comes into direct contact with the eyes, it may cause eye pain, blurring of vision and increased sensitivity to light. It may also cause a more serious eye problem, known as glaucoma, to develop or worsen. The following symptoms may be associated with glaucoma: red eyes, eye pain or discomfort, sight disturbances (blurred vision, visual halos or coloured images). Therefore, it is very important to follow the Directions for Use carefully and avoid contact with the eyes.

Tell your doctor or pharmacist if you begin taking any other medicine while you are using ATROVENT Nasal Aqueous.

If symptoms persist, seek medical advice.

### ***Things you must not do***

Do not use ATROVENT Nasal Aqueous when the medicine is running out and it is no longer possible to obtain a firm spray.

### ***Ability to Drive or Operate Machinery***

If side effects are experienced such as dizziness, blurred vision or dilated pupils (mydriasis) whilst using ATROVENT Nasal Aqueous do not drive or operate machinery.

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### **Side effects**

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You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of using this medicine.

Adverse effects are usually mild to moderate and transient.

Reported side effects of ATROVENT Nasal Aqueous include:

- dryness of the nose, nose bleeds and nasal irritation
- headache, nausea and local irritation (such as a burning sensation)
- dry mouth, sore mouth and swelling of the mouth
- sore throat, discomfort when swallowing (also known as pharyngitis), swelling of the throat and throat irritation (e.g. dry throat)
- infections of the air passages.
- eye disturbances such as red eyes, eye pain or discomfort, blurred vision, visual halos or coloured images, increased sensitivity to light
- fast or irregular heart beat
- change in bowel movements
- urinary retention (difficulty passing urine).
- allergic reactions such as skin rash, swelling of the tongue, lips and face, and difficulty breathing.
- serious allergic (anaphylactoid) reactions have also been reported.

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after using ATROVENT Nasal Aqueous, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after using ATROVENT Nasal Aqueous.

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### **After using ATROVENT Nasal Aqueous**

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#### ***Care and cleaning***

It is recommended that the spray adaptor be cleaned after use.

#### ***Storage***

ATROVENT Nasal Aqueous should be kept in a cool, dry place where the temperature stays below 25°C. Do not store in direct sunlight or heat and protect from freezing.

Keep ATROVENT Nasal Aqueous where young children cannot reach it.

### ***Disposal***

If you do not need ATROVENT Nasal Aqueous any more, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

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### **Product Description**

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#### ***What ATROVENT Nasal Aqueous is***

ATROVENT Nasal Aqueous is the brand name of your medicine. It is a clear, colourless solution in amber glass bottles. Each bottle contains 15 mL of solution, which provides approximately 180 metered doses.

Each spray of ATROVENT Nasal Aqueous contains ipratropium bromide 22 micrograms [equivalent to ipratropium bromide (anhydrous) 21 micrograms] in purified water. It also contains benzalkonium chloride, disodium edetate, sodium chloride (salt), sodium hydroxide and hydrochloric acid.

#### ***Distributor***

ATROVENT Nasal Aqueous is supplied in New Zealand by:

Boehringer Ingelheim NZ Limited  
PO Box 76-216  
Manukau City  
Auckland  
Ph 0800 802461

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# ATROVENT<sup>®</sup> Nasal Aqueous Spray

*Ipratropium bromide Solution 0.03% w/v*

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## Directions for Use

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### **Important Information:**

Read complete directions carefully and use only as directed.

Do not spray in or around your eyes.

Do not pierce the nozzle or attempt to enlarge the hole. The hole in the nozzle is a special size to allow the correct dose of ATROVENT Nasal Aqueous to enter your nostril when you depress the spray pump.

Do not shake the bottle.

### **To Use:**

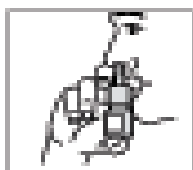
1. Remove protective cap.
2. Before using the spray pump for the first time, rapidly activate the spray pump 5 to 7 times until an even spray mist is released (see Figure 1). Your ATROVENT Nasal Aqueous is now primed and ready for use.



(Figure 1)

With subsequent use, the spray pump is immediately functional. However, if the spray pump has not been used for more than 24 hours, it will require repriming.

3. Blow nose thoroughly before using the nasal spray.
4. Keeping the bottle upright, insert the spray adaptor into the nostril and activate the spray pump firmly while breathing in gently through the nose (see Figure 2). Administer the number of sprays as recommended or as prescribed by your doctor or pharmacist and then repeat in the other nostril.



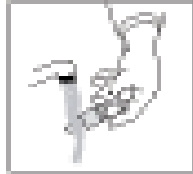
(Figure 2)

5. Replace protective cap after use.

6. Store upright

**To Clean:**

7. If the nasal tip becomes clogged, remove protective cap. Hold the nasal tip under running, warm tap water (see Figure 3) for about a minute. Dry the nasal tip, reprime the nasal pump spray (step 2 above), and replace the protective cap.



(Figure 3)