

Atrovent® Nasal Forte

Ipratropium bromide monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Atrovent Nasal Forte.

It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this information with your nasal spray.

You may need to read it again later.

To find out more about Atrovent Nasal Forte

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 Forte.

What Atrovent Nasal Forte is used for

Atrovent Nasal Forte relieves the symptoms of a persistent runny nose associated with allergic rhinitis (hayfever) & non-allergic non-seasonal rhinitis, and the common cold.

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

Atrovent Nasal Forte is known as an anticholinergic medicine. It belongs to one of several types of medicines used to treat the symptoms of rhinitis and the common cold.

Before you use Atrovent Nasal Forte

When not to use Atrovent Nasal Forte

Do not use Atrovent Nasal Forte 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 Forte 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 Forte if the packaging is torn or shows signs of tampering.

You should never use Atrovent Nasal Forte 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 Forte

Before using Atrovent Nasal Forte, 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 Forte spray contains the (antimicrobial) preservative benzalkonium chloride which may cause irritation of the nasal lining (mucosa).

Before using Atrovent Nasal Forte 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 Forte must be assessed against any risks. Your doctor will discuss the risks and benefits of using Atrovent Nasal Forte 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 Forte may pass into breast milk. The benefits of Atrovent Nasal Forte must be assessed against any risks. Your doctor will discuss the risks and benefits of using Atrovent Nasal Forte while you are breastfeeding.

Children

There is not enough information available to recommend the use of Atrovent Nasal Forte in children under 12 years of age.

Using Atrovent Nasal Forte

How to use Atrovent Nasal Forte

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

Never spray Atrovent Nasal Forte in or around your eyes.

If you accidentally spray Atrovent Nasal Forte 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

For treating symptoms of a runny nose in rhinitis.

Adults and children 12 years of age and over:

1 or 2 sprays into each nostril two or three times daily (at regular intervals).

For treating symptoms of a runny nose in the common cold.

Adults and children 12 years of age and over:

2 sprays into each nostril three or four times daily (at regular intervals).

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

Atrovent Nasal Forte should not be used for longer than 4 days in patients with the common cold.

Do not use extra doses of Atrovent Nasal Forte without consulting your doctor or pharmacist.

If you forget to take a dose

It is important to use Atrovent Nasal Forte 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 Forte.

Immediately telephone your doctor, pharmacist or the Poisons Information Centre (telephone 13 11 26 in Australia).

Do this even if there are no signs of discomfort or poisoning.

Signs of overdose may include increased heart rate, dry mouth and blurred vision.

While using Atrovent Nasal Forte

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 Forte.

If the spray from Atrovent Nasal Forte 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 Forte.

If symptoms persist, seek medical advice.

Things you must not do

Do not use Atrovent Nasal Forte 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 spray do not drive or operate machinery.

Side effects

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 Forte include:

- dryness of the nose, nose bleeds, nasal irritation and congestion
- headache, dizziness, nausea and local irritation (such as a burning sensation)
- dry mouth, sore mouth and swelling of the mouth
- sore throat and discomfort when swallowing (also known as pharyngitis), swelling of the throat and throat irritation (e.g. dry throat).
- changes to your sense of taste
- coughing
- aching muscles, muscle tenderness or weakness, not caused by exercise (also known as myalgia).
- 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 Forte, 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 Forte.

After using Atrovent Nasal Forte

Care and cleaning

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

Storage

Atrovent Nasal Forte 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 Forte where young children cannot reach it.

Disposal

If you will not be needing Atrovent Nasal Forte anymore, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

Product Description

What Atrovent Nasal Forte is

Atrovent Nasal Forte is the brand name of your medicine. It is a clear, colourless solution in amber glass bottles. Each bottle contains 10 mL or 15 mL of solution which provides at least 120 or 180 metered doses.

Atrovent Nasal Forte is identified by an Australian Registration Number and this number appears on the outer carton (AUST R 67490).

Ingredients

Each spray of Atrovent Nasal Forte contains

- 44 micrograms (µg) of ipratropium bromide monohydrate [equivalent to ipratropium bromide 42 micrograms] in purified water.

Other ingredients include:

- benzalkonium chloride as a preservative
- disodium edetate
- sodium chloride (salt)
- sodium hydroxide
- hydrochloric acid.

Manufacturer

Atrovent Nasal Forte is made in Italy and supplied in Australia by:

Sanofi Consumer Healthcare,
87 Yarraman Place, Virginia,
Qld 4014 Australia.

Toll-free: 1800 818 806

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Atrovent® Nasal Forte

Ipratropium bromide monohydrate

Directions For Use

Important Information:

Read complete directions carefully and use only as directed.

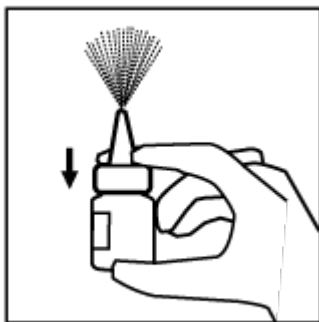
Do not spray in or around your eyes.

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 Forte 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 Forte 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 your 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.



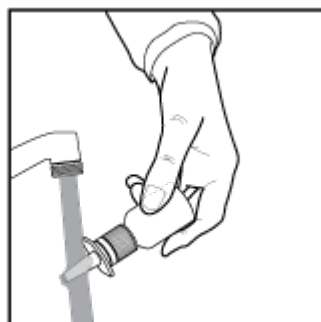
(Figure 2)

5. Replace protective cap after use.

6. Store upright.

7. To Clean:

If the nasal tip becomes clogged, remove the 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)

