

PART III: CONSUMER INFORMATION

Pr **Atrovent® HFA**
(Ipratropium Bromide)
Pressurized Inhalation Solution

Read this carefully before you start taking ATROVENT HFA and each time you get a refill. This leaflet is a summary and will not tell you everything about ATROVENT HFA. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about ATROVENT HFA.

ABOUT THIS MEDICATION**What the medication is used for:**

ATROVENT HFA is used to treat the wheezing or shortness of breath caused by COPD (chronic obstructive pulmonary disease which includes chronic bronchitis and emphysema).

What it does:

ATROVENT HFA belongs to a group of medicines known as “bronchodilators” which make breathing easier by opening your narrowed airways.

When it should not be used:

Do not use ATROVENT HFA if you:

- are allergic to ipratropium bromide or other drugs which are anticholinergic (contain atropine or its derivatives), or to any component of ATROVENT HFA (see “[What the non-medical ingredients are](#)”).
- are under 18 years of age.

ATROVENT HFA should not be used for the treatment of acute episodes of bronchospasm where rapid response is required. If you get a sudden attack of breathlessness, then you should use an additional fast-acting relief medication which has been provided to you by your doctor.

What the medicinal ingredient is:

Ipratropium bromide

What the non-medical ingredients are:

Citric acid, ethanol, propellant (1,1,1,2 - Tetrafluoroethane (HFA 134a)), nitrogen and water.

What dosage forms it comes in:

Pressurized Inhalation Solution 20 mcg/metered dose

WARNINGS AND PRECAUTIONS

BEFORE you use ATROVENT HFA talk to your doctor or pharmacist if you:

- are pregnant or intend to become pregnant;
- are breast feeding;
- have any other health problems;

- have eye problems, such as glaucoma, or eye pain;
- are taking any other medications including eye drops or those you can buy without a prescription;
- have difficulty urinating;
- have cystic fibrosis;
- have any allergies or reactions to foods, drugs or aerosols.

ATROVENT HFA is not recommended for use in children and adolescents under 18 years of age.

Contact your doctor immediately if:

- you require more than one dose to relieve your breathing problems;
- your shortness of breath becomes worse;
- you don't get the same benefit from your medicine as you did before;
- you have breathing difficulties and chest pain;
- you experience difficulty with urination.

ATROVENT HFA may cause dizziness, difficulty in focusing the eyes, dilated pupils, and blurred vision. You should not drive or operate machinery if this occurs.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with ATROVENT HFA:

- other anticholinergic drugs, such as ipratropium bromide, tiotropium, glycopyrronium, aclidinium, umeclidinium;
- xanthine derivatives such as theophylline;
- beta₂-adrenergic agents such as salbutamol.

PROPER USE OF THIS MEDICATION

- **ATROVENT HFA pressurized inhalation solution has been prescribed to treat your current condition. DO NOT give it to other people.**
- **DO NOT exceed the number of puffs prescribed by your doctor.**
- **DO NOT use the inhaler more often than your doctor recommends.**
- **DO NOT take any other medication without your doctor's advice. Tell any *other* doctor, dentist, or pharmacist with whom you consult that you are using ATROVENT HFA pressurized inhalation solution.**
- **When using your ATROVENT HFA pressurized inhalation solution with the standard mouthpiece, make sure you do not spray the aerosol into your eyes.**

- **The container is under pressure and should not be opened by force or exposed to temperatures above 50°C.**

Usual adult dose:

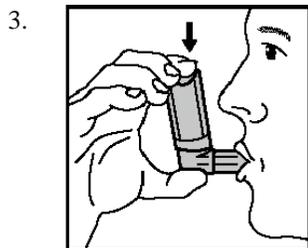
The usual dose is 2 puffs taken up to 3 or 4 times daily. Doses must be taken at least 4 hours apart. Some people may need up to 4 puffs at a time during early treatment. Do not use more than 12 puffs per day.

How to Use Your ATROVENT HFA Pressurized Inhalation Solution:

The plastic mouthpiece has been especially designed for use with ATROVENT HFA pressurized inhalation solution to ensure that you always get the right amount of the medicine. The mouthpiece must never be used with any other pressurized inhalation solution nor must the ATROVENT HFA pressurized inhalation solution be used with any mouthpiece other than the one supplied with the product.

If you are troubled with mucus try to clear your chest as completely as possible by coughing before you use ATROVENT HFA pressurized inhalation solution. This will allow the ATROVENT HFA pressurized inhalation solution to pass more deeply into your lungs.

1. Remove the protective cap from the inhaler.
2. Press down on the top of the inhaler twice to release 2 puffs into the air before the inhaler is used for the first time. If you have not used the inhaler for more than 3 days then only one puff needs to be released before the inhaler is ready to use.



3. Breathe out as completely as possible
 - a) Place the mouthpiece into your mouth and close your lips around it. Keep your teeth apart and your tongue flat to allow free flow the medication into your lungs. The arrow and the base of the container should be pointing upwards.
 - b) Press down on the top of the inhaler and breathe in deeply through your mouth at the same time.

4. Hold your breath for a few seconds, then breathe out slowly.
5. If your doctor has recommended a second puff, wait about one minute and then repeat steps 3 and 4.
6. Replace the protective plastic cap.

Care of the Mouthpiece/Canister:

The container is not transparent. It is therefore not possible to see when it is empty. The inhaler will deliver **200** doses. When these have all been used the inhaler may still appear to contain a small amount of fluid. The inhaler should, however, be replaced because you may not get the right amount of treatment.

The amount of treatment in your inhaler can be checked as follows:



Remove the inner canister from the inhaler. Shake the canister to see if there is any remaining fluid.

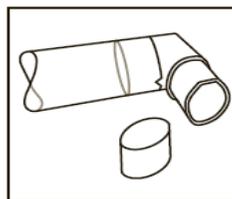
Alternatively remove the canister from the inhaler and put it into a container of water. The contents of the canister can be estimated by observing its position in the water.



Clean your inhaler at least once a week.

It is important to keep the mouthpiece of your inhaler clean to ensure that medicine does not build up and block the spray.

For cleaning, first take off the dust cap and remove the canister from the inhaler. Rinse warm water through the inhaler until no medication build-up and/or dirt is visible.



After cleaning shake out the inhaler and let it air-dry **without** using any heating system. Once the inhaler is dry, replace the canister and the dust cap.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms. Always take the labelled medicine container with you.

Missed Dose:

If you forget to take your dose, don't worry. Take your next dose as usual. Do not double your dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Headache, dizziness
- Nausea (feeling sick), digestive problems like constipation, diarrhea, vomiting

- Impaired voice sounds;
- Throat irritation, cough, dry mouth or throat, bad taste – sucking on a sour candy or rinsing your mouth may help.

If any of these affects you severely, tell your doctor, nurse or pharmacist.

Check with your doctor if the dry mouth or bad taste persist or if you experience constipation for a prolonged period of time

Stop taking the medication and tell your doctor immediately if you notice any of the following:

- you are wheezy or have any other difficulties in breathing;
- you are having an allergic reaction – the signs may include skin rash, itching and nettle rash. In severe cases the signs include swelling of your tongue, lips and face, sudden difficulties in breathing and reduction of your blood pressure.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist immediately		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Uncommon	Bronchospasm: Increased wheezing or tightness in the chest, difficulty in breathing, coughing bouts			✓
	Shortness of breath			✓
	Skin rash			✓
	Allergic reaction: rash, hives, swelling of the face, lips, mouth, tongue or throat, difficulty swallowing or breathing, choking due to swelling of the muscles around the voice box			✓
	Fast or irregular heart beat: a feeling that your heart is beating fast, or skipping a heartbeat			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist immediately		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Eye Disorders: new or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes			✓
Urinary Retention: difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips			✓

This is not a complete list of side effects. For any unexpected effects while taking ATROVENT HFA contact your doctor or pharmacist.

HOW TO STORE IT

- **Keep this medication out of the reach and sight of children.**
- Store at room temperature (15-30°C). Keep from freezing.
- Container may explode if heated. Contents under pressure. Do not place in hot water or near radiators, stoves, or other sources of heat. Do not puncture or incinerate container or store at temperatures over 30°C.
- The expiry date of this medicine is printed on the label. Do not use the medicine after this date.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.boehringer-ingelheim.ca>
or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633 (Medical Information).

Please visit our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

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