

PART III: CONSUMER INFORMATION

Pr **Atrovent® HFA**
(Ipratropium Bromide)
Inhalation Aerosol

This leaflet is part III of a three-part "Product Monograph" published when ATROVENT HFA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ATROVENT HFA. Contact your doctor or pharmacist if you have any questions about the drug.

BEFORE YOU USE ATROVENT HFA INHALATION AEROSOL, YOU SHOULD READ THIS INFORMATION LEAFLET CAREFULLY, EVEN IF YOU HAVE JUST REFILLED YOUR PRESCRIPTION SINCE SOME INFORMATION MAY HAVE CHANGED.

ABOUT THIS MEDICATION

What the medication is used for:

ATROVENT HFA is an aerosol canister with a mouthpiece. It is a bronchodilator and is used for the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including bronchitis and emphysema.

Before you start to use ATROVENT HFA inhalation aerosol, read the following instructions carefully; be sure that you know how to use the inhaler properly. If you use the inhaler incorrectly, you may not be getting all of the medication you need. If you have any questions about using the inhaler, check with your doctor.

What is COPD?

COPD (Chronic Obstructive Pulmonary Disease) is a type of lung disease in which there is a permanent narrowing of the airways, leading to breathing difficulties. In many patients, this narrowing of the airways is a result of many years of cigarette smoking. Smoking cessation produces symptomatic benefits and will slow the progression of chronic bronchitis (which is a form of COPD). COPD can be helped by medication as well.

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:

ATROVENT HFA should not be used by patients with allergic reactions to ipratropium bromide, atropinics or any component of the drug.

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 important non-medicinal ingredients are:

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

What dosage forms it comes in:

Inhalation Aerosol 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;
- if you are breast feeding;
- if you have any other health problems;
- if you have eye problems, such as glaucoma, or eye pain;
- if you are taking any other medications including those you can buy without a prescription.
- if you have any allergies or reactions to foods, drugs or aerosols.

INTERACTIONS WITH THIS MEDICATION

Other medications may be affected by ATROVENT HFA or may affect how ATROVENT HFA works. Do not take any other medication, including over-the-counter medications or herbal products unless your doctor tells you to. Tell any other doctor, dentist or pharmacist that you talk to that you are taking ATROVENT HFA.

PROPER USE OF THIS MEDICATION

DO NOT exceed the number of puffs prescribed by your doctor. DO NOT use the inhaler more often than your doctor recommends.

Usual dose:

The usual dose is 2 puffs taken up to 3 or 4 times daily. Some people may need up to 4 puffs at a time during early treatment. Do not use more than 12 puffs per day unless your doctor has told you to do so.

How To Use Your ATROVENT HFA Inhalation Aerosol

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

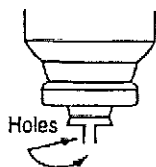
1. Remove the protective cap from the inhaler.
2. The canister should be depressed twice before the inhaler is used for the first time. If the product has not been used for more than 3 days then the canister only needs to be depressed once.
3. Breathe out completely as possible.
 - a) Place the mouthpiece 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.
 - b) Press the canister down into the mouthpiece 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 mouthpiece should be washed with warm water once a week. You must remove the mouthpiece from the canister before you begin to clean the mouthpiece. If you use soap or detergent, the mouthpiece should be well rinsed in clear water, and then allowed to air dry. The mouthpiece must be completely dry before you put the canister back into the mouthpiece.

Sometimes, the canister stem may also get dirty or blocked. Pull the canister out of the mouthpiece and check the small holes in the stem. If these two small holes seem blocked, rinse them with clear lukewarm water. When the canister is dry, put it back into the mouthpiece.



Since the canister is not transparent, it is not possible to see when the contents are used up; shaking the inhaler will allow you to determine if there is any remaining fluid.

Please Remember

1. ATROVENT HFA inhalation aerosol has been prescribed to treat your current condition. **DO NOT** give it to other people.
2. **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 inhalation aerosol.
3. **When using your ATROVENT HFA inhalation aerosol with the standard mouthpiece, make sure you do not spray the aerosol into your eyes.**

Overdose:

If you accidentally take too many puffs, you should get medical

help immediately; either by calling your doctor or by going to the nearest hospital (do not drive yourself). 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.

ATROVENT HFA has been prescribed for you. Do not give it to anyone else, even if you think they have the same condition as you.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any drug product, ATROVENT HFA inhalation aerosol may cause unwanted effects. Do not be alarmed by this list of possible side effects. You may not experience any of them. If you do experience any unusual or unwanted effects while you are using ATROVENT HFA you should contact your doctor or pharmacist immediately.

The most commonly reported undesirable effects of ATROVENT are:

- Dry Mouth
- Headache
- Dizziness
- Constipation
- Vomiting
- Diarrhea
- Cough
- Irritation of mouth and/or throat

If you experience a dry mouth or bad taste, sucking on a sour candy or rinsing your mouth may help. Check with your doctor if the dry mouth or bad taste persist or if you experience constipation for a prolonged period of time.

If your symptoms get worse, contact your doctor immediately. While taking ATROVENT HFA inhalation aerosol, other inhaled medications should be used only as prescribed by your physician.

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

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking ATROVENT HFA, **stop** taking this medicine and tell your doctor immediately or go to the nearest hospital.

- Sudden wheeziness and chest pain or tightness.
- Swelling of eyelids, face, tongue or throat.
- Lumpy skin rash or "hives" anywhere on the body.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	Increased wheezing or tightness in the chest or difficulty in breathing (bronchospasm)			✓
				✓
Uncommon	Swelling of the tongue, lips or face			✓
	Difficulty in swallowing			✓
	Fast or irregular heart beat			✓
	Blurred vision or pain in the eyes			✓
	Difficult or painful urination			✓
	Skin rash/hives			✓

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 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

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
 By toll-free fax: 866-678-6789
 Online: www.healthcanada.gc.ca/medeffect
 By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
 Canada Vigilance National Office
 Marketed Health Products Safety and Effectiveness
 Information Bureau
 Marketed Health Products Directorate
 Health Products and Food Branch
 Health Canada
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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-ingenelheim.ca](http://www.boehringer-ingenelheim.ca)
 or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800- 263-5103, ext. 4633 (Medical Information). Please visit our website to see if more up-to-date information has been posted.

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