

**PART III: CONSUMER INFORMATION****Pr Spiriva® Respimat®**

Tiotropium Bromide Monohydrate Inhalation Solution

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

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

SPIRIVA RESPIMAT is used long term to help open the airways of people with breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD). It is also used to reduce the likelihood of “flare-ups” in people with COPD. In COPD, a “flare-up” is when your condition is getting worse. You will know you are having a “flare-up” if two of the following symptoms get worse for more than two days:

- Unusual increase in the severity of breathlessness; cough, wheezing, or fatigue;
- Unusual colour, amount or thickness of mucus;
- Tightness in the chest or symptoms of a cold.

**Asthma**

SPIRIVA RESPIMAT is used only as add-on therapy to an inhaled corticosteroid and a long-acting beta agonist when those medications are not adequate to control your asthma.

When used to treat asthma, you should use SPIRIVA RESPIMAT in addition to another anti-asthma inhaler as prescribed by your doctor.

**What it does:**

SPIRIVA RESPIMAT contains tiotropium which belongs to a group of medicines called bronchodilators. SPIRIVA RESPIMAT helps the muscles around the airways in your lungs stay relaxed making it easier for air to get in and out of the lungs. When you inhale it, it helps you breathe more easily.

In COPD patients, it also helps to prevent flare-up symptoms, such as wheezing, cough, chest tightness and shortness of breath.

**When it should not be used:**

Do not take SPIRIVA RESPIMAT:

- if you are allergic to ipratropium bromide or other drugs which are anticholinergic (contain atropine or its derivatives) or to any component of SPIRIVA RESPIMAT;
- without also taking an inhaled corticosteroid and a long-acting beta-agonist if you are being treated for asthma.
- if you are under 18 years of age.

SPIRIVA RESPIMAT is not a rescue medicine and should not be used on as needed basis for treating sudden breathing problems during exacerbations (flare-ups or asthma attack) of the disease. Your doctor may give you other medicine to use for sudden breathing problems.

**What the medicinal ingredient is:**

Tiotropium bromide monohydrate

**What the non-medicinal ingredients are:**

Benzalkonium chloride, disodium edetate, hydrochloric acid and purified water.

**What dosage forms it comes in:**

Inhalation Solution

Each puff delivers 2.5 mcg tiotropium from the mouthpiece (as tiotropium bromide monohydrate).

**WARNINGS AND PRECAUTIONS**

The solution is intended for inhalation only. Avoid getting the mist into your eyes. This may result in eye pain and/or discomfort, temporary blurring of vision, and/or coloured images in association with red eyes. Should any of these symptoms develop, consult a doctor immediately.

BEFORE you use SPIRIVA RESPIMAT talk to your doctor or pharmacist if:

- you are pregnant or intend to become pregnant;
- you are breast-feeding;
- you are using any medications including eye drops, other bronchodilators or medications you can buy without a prescription;
- you have any other medical problems such as difficult urination or enlarged prostate;
- you have eye problems, such as glaucoma, or

- eye pain;
- you have any allergies to food or drugs;
- you have kidney disease;
- you have unstable heart disease;
- you have any other medical problems.

SPIRIVA RESPIMAT is indicated for the treatment of COPD and asthma. Do not use this medicine to treat a sudden attack of breathlessness or wheezing. Your doctor should have given you another inhaler ("rescue medication") for this. Please follow the instructions your doctor has given you.

If you have been prescribed SPIRIVA RESPIMAT for your asthma, it should be added on to your inhaled corticosteroid and a long-acting beta-agonist medications. Continue taking your other medications as prescribed by your doctor, even if you feel better.

Your doctor will recommend when and how you should use SPIRIVA RESPIMAT. You must follow any other direction that your doctor has given you for the treatment and/or monitoring of your condition.

Contact your doctor immediately if:

- you require more than one dose (2 actuations) per day 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.

SPIRIVA RESPIMAT may cause dizziness, difficulty in focusing the eye, 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.

SPIRIVA RESPIMAT should not be used together with other medicines containing a short- or long-acting muscarinic blocker as an overdose may result. For example, these other medicines include ipratropium, tiotropium, glycopyrronium, aclidinium, umeclidinium.

## PROPER USE OF THIS MEDICATION

SPIRIVA RESPIMAT has been prescribed to treat your current condition. DO NOT give it to other people. Always use SPIRIVA RESPIMAT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Appropriate use of SPIRIVA RESPIMAT includes an understanding of the way it should be administered. Therefore, it is important that you read and understand how to use the inhaler before starting SPIRIVA RESPIMAT therapy.

It is very important that you use SPIRIVA RESPIMAT regularly every day. Do not stop taking SPIRIVA RESPIMAT suddenly even if you feel better.

### FOR ORAL INHALATION ONLY

Take care to avoid spraying SPIRIVA RESPIMAT into your eyes.

### Usual Adult Dose:

#### **COPD**

Take 2 puffs once a day, if possible at the same time of the day, every day.

#### **Asthma**

Take 2 puffs once a day, if possible at the same time of the day, every day.

In the treatment of asthma, the full benefits will be seen after several doses of SPIRIVA RESPIMAT.

### **Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### Missed dose:

If you forget to inhale a dose, inhale the next dose as soon as possible but do not inhale two doses on the same day. Then inhale the next dose as usual.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Cough, dry mouth or throat, bad taste;
- Dizziness;
- Hoarse voice;
- Rash, itching;
- Difficulty in sleeping;
- Heartburn;
- Constipation;
- Sore throat;
- Sinus infection;
- Inflammation of the mouth, gums and/or tongue;
- Nosebleed;
- Infections or ulcerations of the skin;
- Dry skin.

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

## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
<b>Uncommon (&lt; 1/100 patients)</b>	<b>Urinary Retention:</b> difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips	√	
	<b>Oropharyngeal Candidiasis:</b> fungal infection of the oral cavity and throat	√	
	<b>Skin rash/hives</b>	√	

## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
<b>Paradoxical Bronchospasm:</b> tightness of the chest associated with coughing, wheezing, or breathlessness immediately after inhalation			√
<b>Rare (&lt;1 /1000 patients)</b>			
<b>Serious Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
<b>Urinary tract infection</b>		√	
<b>Difficulty in swallowing</b>			√
<b>Fast or irregular heart beat</b>			√
<b>Eye disorders:</b> new or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes			√
<b>Not Known</b>			
<b>Swelling of joints</b>	√		
<b>Dehydration</b>	√		
<b>Intestinal Obstruction:</b> absence of bowel movements			√

*This is not a complete list of side effects. For any unexpected effects while taking SPIRIVA RESPIMAT, contact your doctor, nurse or pharmacist.*

## HOW TO STORE IT

Store SPIRIVA RESPIMAT between 15-30°C.

Do not freeze your SPIRIVA RESPIMAT cartridge and inhaler.

Keep your SPIRIVA RESPIMAT cartridge and inhaler out of the sight and reach of children.

## 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](http://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](http://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-ingenelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

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

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

Last revised: June 17, 2016

## INSTRUCTIONS FOR USE

2  
PUFFS  
ONCE A  
DAY

### Introduction

Read these **Instructions for Use** before you start using SPIRIVA RESPIMAT.

You will need to use the inhaler only ONCE A DAY. Each time you use it take 2 PUFFS.

Each box contains:

- 1 RESPIMAT inhaler
- 1 cartridge

Each cartridge provides 60 puffs (30 doses). Physician samples and hospital packs provide 28 puffs (14 doses).

The colour of the cap of the RESPIMAT inhaler is colour coded to match the cartridge.



### How to store my SPIRIVA RESPIMAT inhaler

Store SPIRIVA RESPIMAT (the cartridge and inhaler) between 15-30°C. Do not freeze.

Keep out of the sight and reach of children.

Do not use your inhaler after the expiry date.

Do not touch the piercing element inside the clear base.

If you have not used your inhaler in more than:

- 7 days: release 1 puff towards the ground
- 21 days: repeat steps 4 to 6 under “Prepare for first Use” until a cloud is visible. Then repeat steps 4 to 6 three more times.

### How to care for your SPIRIVA RESPIMAT

Clean the mouthpiece including the metal part inside the mouthpiece with a damp cloth or tissue only. You should do this at least once a week. Any minor changes in the colour of the mouthpiece will not affect how your SPIRIVA RESPIMAT works.

### When to get a new SPIRIVA RESPIMAT



- Your SPIRIVA RESPIMAT inhaler contains either 60 puffs (30 doses) or 28 puffs (14 doses) if use it as directed (2 puffs/once a day). The 28 puff (14 dose) product is for physician samples and the hospital pack.
- The dose indicator shows you about how much medication is left.
- When the dose indicator **enters** the red area of the scale, there is about:
  - 7 days of medication left for the 60 puff product
  - 3 days of medication left for the 28 puff product.You need to get a new prescription or refill your prescription.
- Once the dose indicator reaches the **end** of the red scale:
  - Your SPIRIVA RESPIMAT locks automatically. No more doses can be released. At this point, the clear base cannot be turned any further.
- You should throw out the SPIRIVA RESPIMAT when one of the following happens first:
  - 3 months after first use, even if all the medication has not been used, or
  - it locks automatically.

## Prepare for First Use

1

- **Remove clear base**
- Keep the cap closed.
- Press the safety catch while firmly pulling off the clear base with your other hand.



2

- **Insert cartridge**
- Insert the **narrow** end of the cartridge into the inhaler.
- Place the inhaler on a firm surface and push down firmly until it snaps into place.
- You should hear a **“click”** when it has gone in all the way.



3

- **Replace clear base**
- Put the clear base back into place until it **“clicks”**.
- Do not remove the clear base again.



4

- **Turn**
- Keep the cap closed.
- Turn the clear base in the direction of the arrows on the label until it **“clicks”** (half a turn).



5

**Open**

- Open the cap until it snaps fully open.



6

**Press**

- Point the inhaler toward the ground.
- Press the dose-release button.
- Close the cap.
- Repeat steps 4 to 6 **until** a cloud is visible.
- **After a cloud is visible**, repeat steps 4 to 6 three more times.



**Your inhaler is now ready to use.**

## Daily Use

### TURN

- Keep the cap closed.
- **TURN** the clear base in the direction of the arrows on the label until it “clicks” (half a turn).



### OPEN

- **OPEN** the cap until it snaps fully open.



### PRESS

- Breathe out slowly and fully.
- Close your lips around the mouthpiece without covering the air vents.
- While taking a slow, deep breath through your mouth, **PRESS** the dose-release button and continue to breathe in.
- Hold your breath for 10 seconds or for as long as you feel comfortable.



To take your second puff, repeat the 3 steps, TURN, OPEN and PRESS (TOP) one more time.  
Close the cap.



## Answers to Common Questions

It is difficult to insert the cartridge deep enough:

**Did you accidentally turn the clear base before inserting the cartridge?** Open the cap, press the dose-release button, then insert the cartridge.

**Did you insert the cartridge with the wide end first?** Insert the cartridge with the narrow end first.

The dose indicator on the SPIRIVA RESPIMAT reaches zero too soon:

**Did you use SPIRIVA RESPIMAT as indicated (2 puffs/once daily)?** SPIRIVA RESPIMAT will last 30 days if used at 2 puffs once daily. Physician samples and hospital packs will last 14 days if used at 2 puffs once daily.

**Did you turn the clear base before you inserted the cartridge?** The dose indicator counts each turn of the clear base regardless whether a cartridge has been inserted or not.

**Did you spray in the air often to check whether the SPIRIVA RESPIMAT is working?** Once you have prepared SPIRIVA RESPIMAT, no test-spraying is required if used daily.

**Did you insert the cartridge into a used SPIRIVA RESPIMAT?** Always insert a new cartridge into a **NEW** SPIRIVA RESPIMAT.

I cannot press the dose-release button:

**Did you turn the clear base?** If not, turn the clear base in a continuous movement until it clicks (half a turn).

**Is the dose indicator on the SPIRIVA RESPIMAT pointing to zero?** The SPIRIVA RESPIMAT inhaler is locked after 60 puffs (30 doses). Physician samples and hospital packs will be locked after 28 puffs (14 doses). Prepare and use your new SPIRIVA RESPIMAT inhaler.

My SPIRIVA RESPIMAT doesn't spray:

**Did you insert a cartridge?** If not, insert a cartridge.

**Did you repeat Turn, Open, Press (TOP) less than three times after inserting the cartridge?** Repeat Turn, Open, Press (TOP) three times after inserting the cartridge as shown in steps 4 to 6 under "Prepare for first Use".

**Is the dose indicator on the SPIRIVA RESPIMAT pointing to 0?** If the dose indicator points to 0, you have used up all your medication and the inhaler is locked.

Once your SPIRIVA RESPIMAT is assembled, do not remove the clear base or the cartridge. Always insert a new cartridge into a **NEW** SPIRIVA RESPIMAT.

I cannot turn the clear base:

**Did you turn the clear base already?** If the clear base has already been turned, follow steps "OPEN" and "PRESS" under the directions for "Daily Use" to get your dose.

**Is the dose indicator on the SPIRIVA RESPIMAT pointing to zero?** The SPIRIVA RESPIMAT inhaler is locked after 60 puffs (30 doses). Physician samples and hospital packs will be locked after 28 puffs (14 doses). Prepare and use your new SPIRIVA RESPIMAT inhaler.

My SPIRIVA RESPIMAT sprays automatically:

**Was the cap open when you turned the clear base?** Close the cap, then turn the clear base.

**Did you press the dose-release button when turning the clear base?** Close the cap so the dose-release button is covered, then turn the clear base.

**Did you stop when turning the clear base before it clicked?** Turn the clear base in a continuous movement until it clicks (half a turn).