

## PART III: CONSUMER INFORMATION

### PrInspiolto™ Respimat®

Tiotropium (as Tiotropium Bromide Monohydrate) / Olodaterol  
(as Olodaterol Hydrochloride) Inhalation Solution

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

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

INSPIOLTO RESPIMAT is a combination of two medicines that are used to make breathing easier for people who experience breathing difficulties due to a lung disease called Chronic Obstructive Pulmonary Disease or COPD (including chronic bronchitis and emphysema).

#### **What it does:**

INSPIOLTO RESPIMAT contains two active ingredients: Tiotropium, a long-acting muscarinic antagonist (LAMA), and Olodaterol, a long-acting beta<sub>2</sub>-adrenergic agonist (LABA).

Tiotropium and olodaterol relax the muscles in the walls of small airways in the lungs. Both of these medicines work together to help open the airways and make it easier for air to get in and out of the lungs. When taken as prescribed, tiotropium and olodaterol help keep the airways open, which can help prevent shortness of breath and wheezing.

#### **When it should not be used:**

**Do not use INSPIOLTO RESPIMAT:**

- if you have asthma;
- to treat sudden symptoms of COPD;
- if you are allergic to tiotropium bromide, ipratropium bromide or other anticholinergic drugs (containing atropine or its derivatives);
- if you are allergic to olodaterol hydrochloride or other drugs containing a beta agonist;
- if you are allergic to any of the non-medicinal ingredients in the formulation;
- if you are less than 18 years of age.

#### **What the medicinal ingredients are:**

Tiotropium Bromide Monohydrate and Olodaterol Hydrochloride

#### **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 (as tiotropium bromide monohydrate) and 2.5 mcg olodaterol (as olodaterol hydrochloride) from the mouthpiece.

INSPIOLTO RESPIMAT is supplied in a carton containing one INSPIOLTO RESPIMAT cartridge and one INSPIOLTO RESPIMAT inhaler.

The INSPIOLTO RESPIMAT cartridge is only intended for use with the INSPIOLTO RESPIMAT inhaler.

### WARNINGS AND PRECAUTIONS

#### **Warnings – Asthma-Related Death**

You are advised that in patients with asthma, long-acting beta<sub>2</sub>-agonist (LABA) medicines increase the chance of death from asthma problems. In a large asthma study, more patients who used another LABA medicine (salmeterol) died from asthma problems compared with patients who did not use that LABA medicine. This finding may also apply to INSPIOLTO RESPIMAT.

**INSPIOLTO RESPIMAT should only be used to treat COPD.**

**INSPIOLTO RESPIMAT should not be used to treat asthma.**

**BEFORE you use INSPIOLTO RESPIMAT talk to your doctor, nurse or pharmacist if you:**

- have heart problems, such as rapid or irregular heart beat or abnormal electrical signal called “prolongation of the QT interval”;
- have high blood pressure;
- have seizures;
- have thyroid problems;
- have diabetes;
- are taking similar medicines for your lung disease;
- have been told you react strongly to sympathomimetic amines (a class of drugs that includes LABA drugs) or if you are allergic to ipratropium bromide or other drugs which are anticholinergic (contain atropine or its derivatives);
- are taking any medications including eye drops, this includes those you can buy without a prescription;
- have any other medical problems such as difficulty with urination or enlarged prostate;
- have eye problems, such as glaucoma, or eye pain;
- have any allergies to food or drugs;
- have kidney disease;
- are pregnant or planning to become pregnant. It is not known if INSPIOLTO RESPIMAT can harm your unborn baby;
- are breastfeeding. It is not known if INSPIOLTO RESPIMAT passes into your milk and if it can harm your baby.

**During the treatment with INSPIOLTO RESPIMAT, tell your doctor immediately or get emergency medical care if you experience any of the following symptoms:**

- Tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (signs of bronchospasm).
- Difficulties in breathing or swallowing, swelling of tongue, lips and face, hives or itching, skin rash (signs of hypersensitivity reaction). Do not use INSPIOLTO RESPIMAT again before speaking with your doctor.

- Your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen during your treatment.
- Pain or difficulty with urination.

### Other warnings you should know about

**Treatment of COPD:** INSPIOLTO RESPIMAT does not relieve sudden symptoms of COPD. Always have a short-acting bronchodilator medicine with you to treat acute symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your healthcare provider to have one prescribed for you.

**Driving and using machines:** Caution is required when driving a car or operating machinery as dizziness and blurred vision may occur with the use of INSPIOLTO RESPIMAT. If you experience dizziness, you should avoid driving or operating machinery.

### 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 INSPIOLTO RESPIMAT:

- antidepressants, in particular tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs);
- medicines similar to INSPIOLTO RESPIMAT (other short- or long-acting muscarinic antagonists such as ipratropium, tiotropium, glycopyrronium, aclidinium, umeclidinium) used for your lung disease, as an overdose may result;
- medicines that decrease the level of potassium in your blood. These include diuretics (also known as “water pills” and are used to treat high blood pressure e.g. hydrochlorothiazide), other bronchodilators such as methylxanthines (e.g. theophylline) or steroids (e.g. prednisolone);
- beta-blockers used in the treatment of high blood pressure or other heart problems (e.g. propranolol) or in the treatment of glaucoma (e.g. timolol).

### PROPER USE OF THIS MEDICATION

- Read the **Instructions for use** before using INSPIOLTO RESPIMAT and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor, nurse or pharmacist about your medical condition or your treatment.
- Always use the new INSPIOLTO RESPIMAT inhaler that is provided with each new prescription.
- Do not stop using INSPIOLTO RESPIMAT or other medicines to control or treat your COPD unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- Do not spray into eyes.

- Call your healthcare provider or get emergency medical care right away if:
  - your breathing problems worsen with INSPIOLTO RESPIMAT;
  - you need to use your rescue medicine more often than usual;
  - your rescue inhaler medicine does not work as well for you at relieving your symptoms.

### Usual Adult Dose:

The recommended dose of INSPIOLTO RESPIMAT is 2 puffs (5 mcg tiotropium and 5 mcg olodaterol), once daily at the same time of the day, every day.

### 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 miss a dose of INSPIOLTO RESPIMAT, take it as soon as you remember. Do not take more than one dose (two puffs) per day. Then take your next dose as usual.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- increase of the measured eye pressure;
- seeing halos around lights or coloured images in association with red eyes;
- blurred vision;
- diarrhea;
- constipation;
- dry mouth;
- inflammation of the mouth, gums and tongue;
- difficulty in swallowing;
- heartburn;
- feeling tired;
- general weakness;
- inflammation of the throat, nasal passages and sinuses;
- common cold;
- fungal infections of the oral cavity and throat;
- depletion of body water;
- back pain;
- swollen and painful joints;
- muscular pain;
- muscle spasms;
- feeling dizzy;
- difficulty sleeping;
- cough;
- pain in mouth and throat;
- hoarseness;
- nosebleed;
- sore throat and discomfort when swallowing;

- inflammation/irritation of the vocal chords;
- pain when passing urine;
- inability to empty the bladder ;
- rash;
- itching;
- nettle rash;
- infections or ulcerations of the skin;
- dryness of the skin.

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help	
	Only if severe	In all cases		
Uncommon	<b>High or low blood pressure:</b> headache, ringing in the ears, lightheadedness, dizziness, fainting		✓	
	<b>Fast or irregular heartbeat, heart palpitations, prolongation of QT interval</b>		✓	
	<b>Blockage of intestines or absence of bowel movements</b> (intestinal obstruction , including ileus paralytic)		✓	
	<b>Blurred vision or pain in the eyes</b>			✓
	<b>Allergic reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	<b>Bronchospasm:</b> wheezing or coughing and difficulty breathing			✓
	<b>Urinary tract infection:</b> pain and burning when urinating, frequent urination		✓	
Rare	<b>Swelling of the feet, ankles or legs (edema peripheral)</b>		✓	
	<b>Bronchitis:</b> shortness of breath, cough, chest pain		✓	
	<b>Lower respiratory infection:</b> shortness of breath, cough, chest pain		✓	

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

Symptom / effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
<b>Myocardial ischaemia (decreased blood flow to your heart muscle):</b> chest pain, trouble breathing, swelling of the hands or feet, heartburn			✓
Not Known	<b>Chest pain</b>		✓
	<b>High blood sugar:</b> frequent urination, thirst, and hunger	✓	
	<b>Blood pH imbalance (metabolic acidosis):</b> chest pain, headache, heart palpitations, nausea, vomiting, stomach pain		
<b>Low blood potassium:</b> irregular heartbeats, muscle weakness or spasms and generally feeling unwell		✓	

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

### HOW TO STORE IT

Store INSPIOLTO RESPIMAT between 15–30°C.

Do not freeze your INSPIOLTO RESPIMAT cartridge and inhaler.

Keep your INSPIOLTO 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<sup>™</sup> 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 15, 2018

## INSTRUCTIONS FOR USE

2  
PUFFS  
ONCE A  
DAY

### Introduction

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

You will need to use this 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 INSPIOLTO RESPIMAT inhaler

Store INSPIOLTO 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 INSPIOLTO 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 INSPIOLTO RESPIMAT works.

### When to get a new INSPIOLTO RESPIMAT



- Your INSPIOLTO RESPIMAT inhaler contains either 60 puffs (30 doses) or 28 puffs (14 doses) if you 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 INSPIOLTO 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 INSPIOLTO 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:

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

**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 use INSPIOLTO RESPIMAT as indicated (2 puffs/once daily)?** INSPIOLTO 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 insert the cartridge with the wide end first?** Insert the cartridge with the narrow end first.

**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 INSPIOLTO RESPIMAT is working?** Once you have prepared INSPIOLTO RESPIMAT, no test-spraying is required if used daily.

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

I cannot press the dose-release button:

My INSPIOLTO RESPIMAT doesn't spray:

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

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

**Is the dose indicator on the INSPIOLTO RESPIMAT pointing to zero?** The INSPIOLTO 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 INSPIOLTO RESPIMAT inhaler.

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

I cannot turn the clear base:

My INSPIOLTO RESPIMAT sprays automatically:

**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.

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

**Is the dose indicator on the INSPIOLTO RESPIMAT pointing to zero?** The INSPIOLTO 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 INSPIOLTO RESPIMAT inhaler.

**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).