

# RESPIMAT® Soft Mist Inhaler

## Instructions for FIRST-TIME USE and EVERYDAY USE

### Prepare for **FIRST USE**

#### **LOADING** Required once, prior to first use.

##### **TAKE OFF THE CLEAR BASE**



With the cap closed, press down on the safety catch while pulling off the clear base.

##### **INSERT THE CARTRIDGE**



Push the narrow end of the cartridge into the inhaler until it clicks.



Press against a firm surface to ensure that it has gone in as much as possible.

##### **REPLACE THE CLEAR BASE**



Once the cartridge is in, replace the clear base. Do not remove the cartridge or clear base again.



The cartridge won't be flush with the inhaler. The silver ring at the end of the cartridge will still be visible.

### **PRIMING**

##### **T** **TURN**



Hold the inhaler upright with the cap closed. **TURN** the clear base a half turn in the direction of the arrows on the label until it clicks.

##### **O** **OPEN**



**OPEN** the cap until it snaps fully open and point the inhaler at the ground.

##### **P** **PRESS**



**PRESS** the dose-release button, close the cap and repeat the steps of **TURN, OPEN, PRESS (TOP)** until you see a cloud.

**After a cloud is visible, repeat TOP three more times and your inhaler is ready for use.**

# Instructions for EVERYDAY USE

## USING

### T TURN



With the cap closed, hold the inhaler upright and **TURN** the clear base in the direction of the arrows on the label until it clicks.

### O OPEN



**OPEN** the cap until it snaps fully open. Breathe out slowly and fully. Close lips around the mouthpiece and point to the back of the throat, making sure the air vents aren't blocked.

### P PRESS



While taking a deep, slow breath through the mouth, **PRESS the dose-release button and continue to breathe in.**

Hold your breath for 10 seconds or for as long as you feel completely comfortable. To take your second puff, repeat the 3 steps, **TURN, OPEN, PRESS (TOP)**, one more time. When finished, close the cap.

**If you haven't used your RESPIMAT inhaler daily as prescribed,** review the instructions that came with your inhaler to see if you need to take any additional steps before using your inhaler again.

### Share your experience.

Talk to your doctor or pharmacist about your experience with the RESPIMAT inhaler.

Ask your doctor or pharmacist for help when **loading or priming your inhaler.**

Remember, you can always talk to him/her to learn more.



- Talk to your doctor or pharmacist if you have any questions or need additional help and support.
- Ask for help when you set up your inhaler.
- Ask your doctor about respiratory therapists (RTs) in your area. They're experts in respiratory therapy and can offer specialized help and support.

Visit [www.learntouse.ca/Matt](http://www.learntouse.ca/Matt) to learn more about how to use your RESPIMAT inhaler

- Watch instructional videos that are available in different languages
- Chat with Matt, the RESPIMAT chatbot



To learn more about your disease, upcoming lung disease programs in your area, and answers to your health questions, visit [www.lung.ca](http://www.lung.ca) or contact the **Lung Association (1-866-717-2673)**.

## 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 healthcare professional 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 heartbeat 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.

Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

**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 healthcare 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.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
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>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	<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		✓	
	<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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

***NOTE:** Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

### If you want more information about INSPIOLTO RESPIMAT:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), the manufacturer's website (<https://www.boehringer-ingelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

Last revised: November 14, 2019



## INSTRUCTIONS FOR USE

### 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 doses) 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.
- **T**URN the clear base in the direction of the arrows on the label until it “clicks” (half a turn).



### OPEN

- **O**PEN the cap until it snaps fully open.

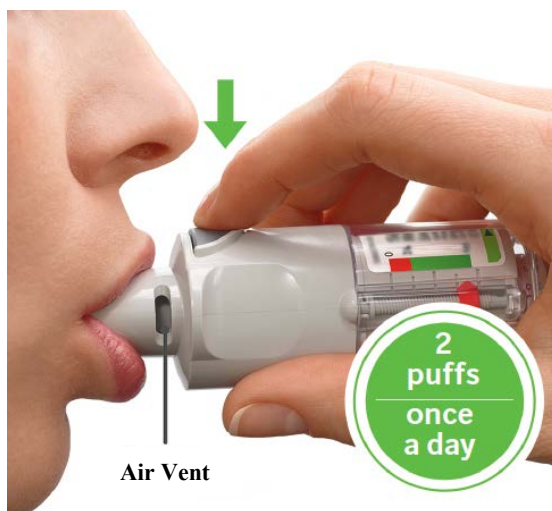


### PRESS

- 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, **P**RESS 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 zero?** If the dose indicator points to zero, 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).

**PART III: CONSUMER INFORMATION****PrSpiriva® 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 healthcare professional 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.

Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

## 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:**

If you think you have taken too much SPIRIVA RESPIMAT, contact your healthcare professional, 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, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Uncommon (<1/100 patients)	<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, nurse 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			✓
Rare (<1/1000 patients)	<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			✓
Not Known	<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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

### If you want more information about SPIRIVA RESPIMAT:

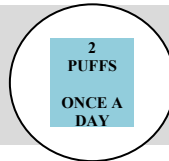
Talk to your healthcare professional.

Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (<https://www.boehringer-ingelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, extension 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

Last revised: May 7, 2019

**INSTRUCTIONS FOR USE**



**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 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 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.
- **T**URN the clear base in the direction of the arrows on the label until it “clicks” (half a turn).



### OPEN

- **O**PEN 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, **P**RESS 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 SPIRIVA 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 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 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 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:

My SPIRIVA 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 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.

**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:

My SPIRIVA 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 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.

**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).

## PART III: CONSUMER INFORMATION

### PrCombivent® Respimat®

Ipratropium Bromide (as Monohydrate)/Salbutamol  
(as Salbutamol Sulfate) Inhalation Solution

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

### ABOUT THIS MEDICATION

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

COMBIVENT RESPIMAT 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:**

COMBIVENT RESPIMAT is a combination of two drugs that are bronchodilators: ipratropium bromide (an anticholinergic) and salbutamol (a beta-agonist). COMBIVENT RESPIMAT works by relaxing the muscle surrounding the bronchi (airways in the lungs) and therefore helps to ease breathing problems.

You may already be familiar with one or both of these bronchodilators, since they are also available separately, with a prescription as ipratropium bromide and salbutamol.

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

Do not take COMBIVENT RESPIMAT if:

- you are allergic to ipratropium bromide or other drugs which are anticholinergic (contain atropine or its derivatives), salbutamol sulfate, or to any component of COMBIVENT RESPIMAT (see “**What the non-medicinal ingredients are**”);
- you have a fast or irregular heart beat or have a thickened heart muscle due to various conditions;
- you are under 18 years of age.

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

Ipratropium bromide monohydrate and salbutamol sulfate.

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

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

#### **What dosage forms it comes in:**

Inhalation Solution.

Each puff delivers 20 mcg ipratropium bromide (monohydrate) and 100 mcg salbutamol (as salbutamol sulfate) from the mouthpiece.

The inhaler enables you to inhale the medicine contained in a cartridge. The cartridge contains 120 puffs or 60 puffs (equal to 120 doses of medicine or 60 doses of medicine) available after preparing the inhaler for first use. There is enough medicine for 30 days or 15 days when it is used as 1 puff four times a day.

### WARNINGS AND PRECAUTIONS

The solution is intended for inhalation only.

Avoid getting the spray 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 COMBIVENT RESPIMAT talk to your doctor or pharmacist if you:**

- are pregnant or intend to become pregnant;
- are breast feeding;
- are having treatment for a thyroid or adrenal gland condition;
- are having treatment for high blood pressure, angina or a heart problem;
- have diabetes;
- have low levels of potassium in your blood (hypokalemia), especially if you are taking:
  - drugs known as xanthine derivatives (such as theophylline);
  - steroids to treat asthma;
  - water pills (diuretics);
- have eye problems, such as glaucoma, or eye pain;
- are taking any other medications including eye drops or any medications you can buy without a prescription;
- have difficulty in urination;
- have enlarged prostate;
- have any allergies or reactions to foods or drugs;
- have a history of convulsions (uncontrolled shaking or seizures);
- have liver or kidney disease.

Contact your doctor immediately if:

- you require more than 1 daily dose (4 puffs); the maximum daily dose is 6 puffs;
- 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.

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

The use of COMBIVENT RESPIMAT may test positive for performance enhancement (doping) in athletic competition.

Benzalkonium chloride may cause wheezing and breathing

difficulties (bronchospasm), especially if you have asthma.

## 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 COMBIVENT RESPIMAT:

- digitalis;
- other anticholinergic drugs, such as ipratropium bromide and other beta<sub>2</sub>-adrenergic agents such as salbutamol, the individual ingredients of COMBIVENT RESPIMAT;
- beta blockers, such as propranolol;
- xanthine derivatives such as theophylline;
- monoamine oxidase inhibitors such as isocarboxazid;
- tricyclic antidepressants such as amitriptyline;
- epinephrine;
- certain diuretics or “water pills” such as furosemide, hydrochlorothiazide.

## PROPER USE OF THIS MEDICATION

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

Appropriate use of COMBIVENT 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 COMBIVENT RESPIMAT therapy.

Dosage should be individualized.

Not recommended for use in children and adolescents under 18 years of age.

### FOR ORAL INHALATION ONLY

Take care to avoid spraying COMBIVENT RESPIMAT into your eyes.

#### Usual Adult Dose:

1 puff four times a day.

Patients may take additional inhalations as required; however, the total number of inhalations should not exceed six in 24 hours.

#### Overdose:

If you think you have taken too much COMBIVENT RESPIMAT, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### Missed dose:

If a dose is missed and no symptoms occur, the regular next dose according to the dosing schedule should be taken. If a dose is missed and respiratory symptoms are experienced, the missing dose should be taken and the dosing schedule according to the recommended dosage should be resumed.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- wheezing after inhalation;
- headache, dizziness;
- nausea (feeling sick), digestive problems like constipation, diarrhoea and vomiting;
- muscle problems such as cramps, weakness, pain, feeling weak, tremor (shaking);
- feeling nervous;
- mental disorder;
- impaired voice sounds;
- increased sweating;
- bronchitis and upper respiratory tract infection (a cold);
- throat irritation, cough, dry mouth or throat, bad taste - sucking on a sour candy or rinsing your mouth may help.

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

COMBIVENT RESPIMAT contains a beta-agonist, and taking additional doses in the form of other single agent, beta-agonists (fenoterol, salbutamol, etc.) could cause harmful effects on the heart, lungs and circulatory system. Therefore do not take additional bronchodilators by inhalation with COMBIVENT RESPIMAT unless instructed to do so by your doctor or pharmacist.

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.

COMBIVENT RESPIMAT can cause abnormal blood test results for hypokalemia and/or ketoacidosis. Your doctor will decide when to perform blood tests and will interpret the results.

**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</b>	<b>Bronchospasm:</b> increased wheezing or tightness in the chest, difficulty in breathing, coughing bouts		✓
	<b>Shortness of breath</b>		✓
	<b>Hypotension or hypertension, changes in blood pressure:</b> dizziness, fainting, lightheadedness		✓
	<b>Skin rash</b>		✓
<b>Rare</b>	<b>Allergic reaction:</b> 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		✓
	<b>Fast or irregular heart beat / chest pain</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>Urinary Retention:</b> difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips		✓
	<b>Muscle pain, weakness or spasms; paralysis</b>		✓
	<b>Myocardial ischaemia:</b> decreased blood flow to the heart leading to angina (chest pain), shortness of breath, or a heart attack		✓
	<b>Angina:</b> chest pain		✓

**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>Decreased levels of potassium in the blood:</b> irregular heartbeats, muscle weakness and generally feeling unwell			✓

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

**HOW TO STORE IT**

Store at room temperature (25°C), excursions permitted to 15-30°C. Do not freeze.

Store out of the sight and reach of children.

COMBIVENT RESPIMAT should be discarded whenever one of the following occurs first:

- at the latest, three months after you first use it (even if not all medication has been used);
- when the locking mechanism is enacted.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

### If you want more information about COMBIVENT RESPIMAT:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), the manufacturer's website (<https://www.boehringer-ingenheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, extension 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

Last revised: November 7, 2019

1  
PUFF  
FOUR  
TIMES A  
DAY

## INSTRUCTIONS FOR USE

### Introduction

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

You will need to use this inhaler **FOUR TIMES A DAY**. Each time you use it take 1 PUFF.

Each box contains:

- 1 RESPIMAT inhaler
- 1 cartridge

Each cartridge provides 120 puffs (120 doses). Physician samples provide 60 puffs (60 doses).

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



### How to store my COMBIVENT RESPIMAT inhaler

Store COMBIVENT 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:

- 3 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 COMBIVENT 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 COMBIVENT RESPIMAT works.

### When to get a new COMBIVENT RESPIMAT



- Your COMBIVENT RESPIMAT inhaler contains either 120 puffs (120 doses) or 60 puffs (60 doses) if you use it as directed (1 puff / four times a day). The 60 puffs (60 doses) product is for physician samples.
- 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 120 puff product;
  - 3 days of medication left for the 60 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 COMBIVENT 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 COMBIVENT 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.

Close the cap.



## Answers to Common Questions

It is difficult to insert the cartridge deep enough:

The dose indicator on the COMBIVENT 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 COMBIVENT RESPIMAT as indicated (1 puff/four times a day)?** COMBIVENT RESPIMAT will last 30 days if used at 1 puff four times a day. Physician samples will last 15 days if used at 1 puff four times a day.

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

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

I cannot press the dose-release button:

My COMBIVENT 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 COMBIVENT RESPIMAT pointing to zero?** The COMBIVENT RESPIMAT inhaler is locked after 120 puffs (120 doses). Physician samples will be locked after 60 puffs (60 doses). Prepare and use your new COMBIVENT 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 COMBIVENT 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 COMBIVENT RESPIMAT is assembled, do not remove the clear base or the cartridge. Always insert a new cartridge into a **NEW** COMBIVENT RESPIMAT.

I cannot turn the clear base:

My COMBIVENT 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 COMBIVENT RESPIMAT pointing to zero?** The COMBIVENT RESPIMAT inhaler is locked after 120 puffs (120 doses). Physician samples will be locked after 60 puffs (60 doses). Prepare and use your new COMBIVENT 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).