

**PART III: CONSUMER INFORMATION**

**Pr Spiriva®**  
**Tiotropium**  
**Capsules for Oral Inhalation**  
**(18 µg tiotropium per capsule as**  
**tiotropium bromide monohydrate)**

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

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

SPIRIVA is a long-acting bronchodilator for maintenance treatment of bronchospasm associated with Chronic Obstructive Pulmonary Disease (COPD).

**What it does:**

SPIRIVA contains tiotropium which belongs to a group of medicines called bronchodilators. SPIRIVA helps the muscles around the airways in your lungs stay relaxed for 24 hours making it easier for air to get in and out of the lungs. When you inhale it, it helps you breathe more easily.

**When it should not be used:**

Do not take SPIRIVA if you are:

- allergic to ipratropium bromide or other drugs which are anticholinergic (contain atropine or its derivatives) or to any component of SPIRIVA;
- under 18 years of age.

SPIRIVA is not a rescue medicine and should not be used on as needed basis for treating sudden breathing problems during exacerbations (flare-ups) 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:**

Lactose monohydrate (which contains milk protein)

**What dosage forms it comes in:**

Capsules for oral inhalation. **DO NOT SWALLOW.**

Each capsule contains a dry powder blend of 18 µg tiotropium (equivalent to 22.5 µg tiotropium bromide monohydrate) with lactose monohydrate (which contains milk protein) as the carrier. SPIRIVA capsules are light green, with TI 01 printed on one side of the capsule and the Boehringer Ingelheim company logo on the other side. Ten SPIRIVA capsules are packaged in an aluminum /

PVC / aluminum blister card. One blister card consists of two 5-cavity strips joined along a perforated line.

SPIRIVA capsules are partially filled but contain exact amount of medication as declared on the label.

**WARNINGS AND PRECAUTIONS**

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

- You may be pregnant or wish to become pregnant;
- You are a breastfeeding mother;
- You are taking any medications including eye drops, this includes those you can buy without 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 are allergic to lactose (milk sugar);
- You have problems with your kidneys.

These capsules are intended for inhalation only. **DO NOT SWALLOW!**

SPIRIVA should not be used more frequently than once daily. Do not exceed the prescribed dose.

This medication has been prescribed for you and should not be given to other people.

Avoid getting the drug powder 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. These may be signs of acute narrow-angle glaucoma. Should any of these symptoms develop, consult a doctor immediately.

If you have any questions about SPIRIVA or the HandiHaler® device, contact your doctor or pharmacist.

Contact your doctor immediately if:

- you require more than one dose 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.

**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.

Medicines similar to SPIRIVA (other short- or long-acting muscarinic antagonists) used for your lung disease may interact with SPIRIVA and increase the risk of experiencing possible side effects.

**PROPER USE OF THIS MEDICATION**

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

SPIRIVA should be administered once daily by inhalation only through the HandiHaler® inhalation device. The HandiHaler® enables you to inhale the medicine contained in the SPIRIVA capsule that your doctor has prescribed for your breathing problems. The HandiHaler® is especially designed for SPIRIVA; you must not use it to take any other medication. Likewise, you should not take your SPIRIVA capsules with any device other than the HandiHaler®. You can use your HandiHaler® for up to one year to take your medication before needing a replacement. Before starting treatment with SPIRIVA, be certain that you are completely familiar with the use and proper care of the HandiHaler® device.

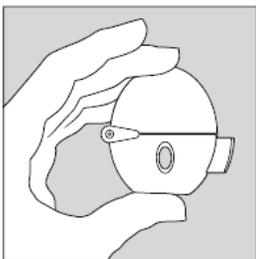
If you are unable to inspire through the HandiHaler® to make the SPIRIVA capsule vibrate, consult your physician.

**Usual dose:**

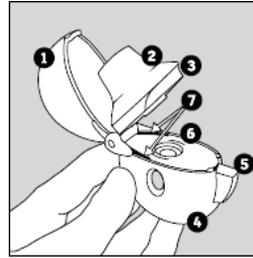
**One (1) SPIRIVA capsule is to be inhaled once daily, preferably at the same time each day, only with the HandiHaler® inhalation device. DO NOT SWALLOW!**

**Do not use another type of inhaler with the SPIRIVA capsules. Do not use other capsules in the HandiHaler® inhalation device.**

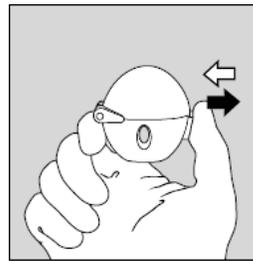
**How to Use SPIRIVA through the HandiHaler® Inhalation Device:**



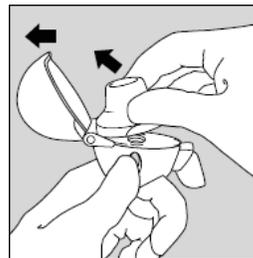
1. Become familiar with the HandiHaler® device.



- 1 Dust cap
- 2 Mouthpiece
- 3 Mouthpiece ridge
- 4 Base
- 5 Piercing button
- 6 Centre chamber
- 7 Air intake vents

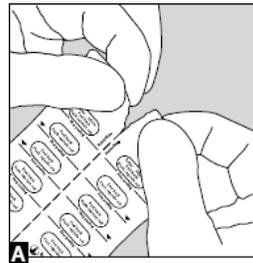


2. To release the dust cap, press the green piercing button completely in and let go.

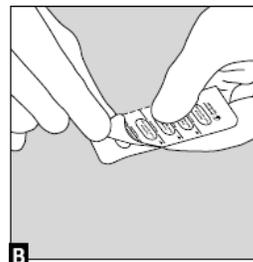


3. Open the dust cap completely by pulling it upwards, then open the mouthpiece by pulling it upwards.

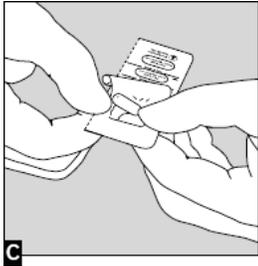
**4. Blister Handling:**



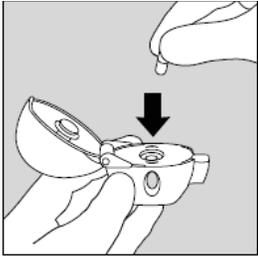
- 4A. The blister card contains two blister strips joined along a perforated line. Prior to removing the first capsule from the blister card, separate the blister strips by tearing along the perforation.



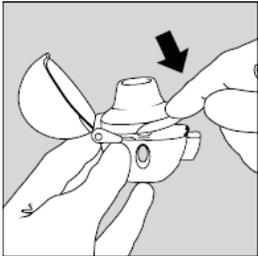
- 4B. **Immediately** before use, peel the aluminum back foil until **one** capsule is fully visible. After opening a strip, the in-use shelf life of the remaining capsules in the strip is 5 days.



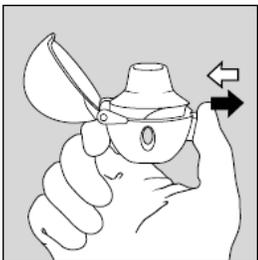
4C. Remove **one** SPIRIVA capsule from the blister. Do not expose more than one capsule. If more than one capsule is exposed, you should discard the exposed unused capsules. Do not store the capsule in the HandiHaler<sup>®</sup> device.



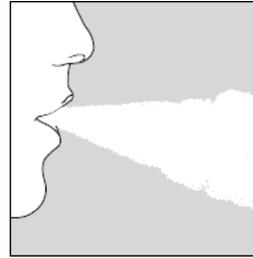
5. Place the capsule in the centre chamber. It does not matter which end of the capsule is placed in the chamber.



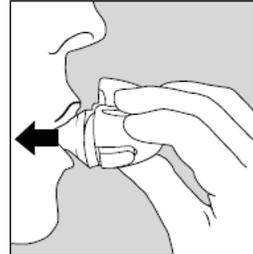
6. Close the mouthpiece **firmly until you hear a click**, leaving the dust cap open.



7. **Hold the HandiHaler<sup>®</sup> with the mouthpiece upwards and press the green piercing button completely in only once, and release.** This makes holes in the capsule and allows the medication to be released when you breathe in.  
The piercing of the SPIRIVA capsule may produce small gelatin pieces. Some of these small pieces may pass through the screen of your HandiHaler<sup>®</sup> device into your mouth or throat when you breathe in your medicine. This is normal. The small pieces of gelatin should not harm you.

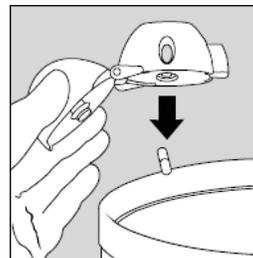


8. If you feel that your chest is congested with mucus, try to cough to clear your lungs before you inhale SPIRIVA. Breathe out completely. **Important: Do not breathe into the mouthpiece at any time.**



9. Hold the HandiHaler<sup>®</sup> by the grey base. **Do not block the air intake vents.** Raise the HandiHaler<sup>®</sup> to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position and breathe in slowly and deeply but at a rate **sufficient to hear or feel the capsule vibrate.** Breathe in until your lungs are full; then hold your breath as long as comfortable (try counting to 10) and at the same time take the HandiHaler<sup>®</sup> out of your mouth. Resume normal breathing.

10. **To ensure complete inhalation of capsule contents, you must repeat steps 8 and 9 once again.**

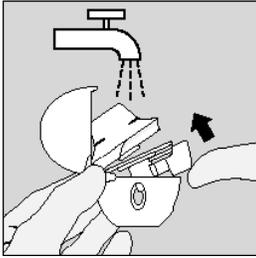


11. Open the mouthpiece again. Tip out the used capsule and dispose. Do not touch the used capsules. If the dry powder gets on your hands, make sure you wash your hands thoroughly.

12. Close the mouthpiece and dust cap for storage of your HandiHaler<sup>®</sup> device.

**When and how should you clean the HandiHaler®?**

It is important to clean the HandiHaler® once a month as follows:



1. Open the dust cap and mouthpiece.
2. Open the base by lifting the piercing button.
3. Rinse the complete inhaler with warm water to remove any powder.
4. Dry the HandiHaler® thoroughly by tipping excess of water out on a paper towel and air-dry afterwards, leaving the dust cap, mouthpiece and base open. It takes 24 hours to air dry, so clean it right after you used it and it will be ready for your next dose. The outside of the mouthpiece may be cleaned with a moist but not wet tissue if needed.

**Do not place HandiHaler® in the dishwasher.**

**Overdose:**

In case of accidental 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 forget to take a dose, take one as soon as you remember but do not take two doses at the same time or on the same day. Then take your next dose as usual.

**Driving and using machines:**

The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery.

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>Oropharyngeal candidiasis:</b> fungal infection of the oral cavity and throat		✓
	<b>Fast or irregular heartbeat</b>		✓
	<b>Skin rash/hives</b>	✓	
	<b>Urinary retention:</b> difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips		✓
<b>Rare (&lt;1 /1000 patients)</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>Paradoxical bronchospasm:</b> tightness of the chest associated with coughing, wheezing, or breathlessness immediately after inhalation (bronchospasm)		✓
	<b>Difficulty in swallowing</b>		✓
	<b>Intestinal obstruction:</b> absence of bowel movements		✓
	<b>Urinary tract infection</b>		✓

**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.

**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>Serious allergic reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
<b>Not Known</b>			
<b>Swelling of joints</b>	✓		
<b>Dehydration</b>	✓		

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

**MORE INFORMATION**

**If you want more information about SPIRIVA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>), the manufacturer’s website (<http://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 24, 2017

**HOW TO STORE IT**

Keep SPIRIVA and your HandiHaler® inhalation device in a cool dry place at room temperature between 15-25°C. Protect from moisture. Do not freeze. The capsules should not be exposed, either in the blister pack or in the inhaler, to extreme temperatures, i.e. they should not be exposed to sunlight or to heat and humidity. Your bathroom or car are not good choices.

**Keep 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.*