

PART III: CONSUMER INFORMATION

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

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

PLEASE READ THIS INFORMATION CAREFULLY AND COMPLETELY BEFORE YOU USE SPIRIVA EVEN IF YOU HAVE JUST REFILLED YOUR PRESCRIPTION, SINCE SOME INFORMATION MAY HAVE CHANGED.

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 is COPD?

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

What it does:

Tiotropium bromide is one of a group of medicines called "bronchodilators".

SPIRIVA makes breathing easier by opening your narrowed airways and keeping them open for 24 hours.

When it should not be used:

SPIRIVA should not be used by patients with a history of allergy to atropine or its derivatives (ipratropium or oxitropium) or to any component of this formulation. (see **What the non-medicinal ingredients are**)

SPIRIVA should not be used as a rescue medication (to treat a sudden attack of breathlessness or wheezing).

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. Should any of these symptoms develop, consult a doctor immediately.

Remember to tell any other doctor, dentist or pharmacist you consult that you are taking this medication.

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

INTERACTIONS WITH THIS MEDICATION

Other medications may be affected by SPIRIVA or may affect how SPIRIVA works. Tell your doctor or pharmacist if you are taking other medications.

PROPER USE OF THIS MEDICATION

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.

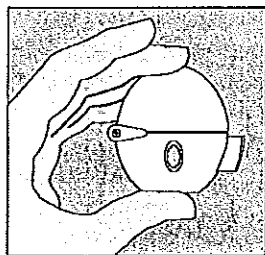
If you are unable to inspire through the HandiHaler® to make the SPIRIVA capsule vibrate, consult your physician.

Usual dose:

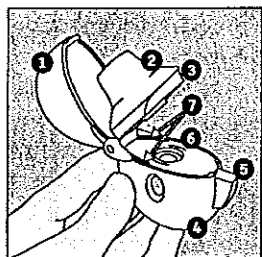
One (1) SPIRIVA capsule is to be inhaled once daily, preferably at the same time each day, only with the HandiHaler® inhalation device. **DO NOT SWALLOW!**

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

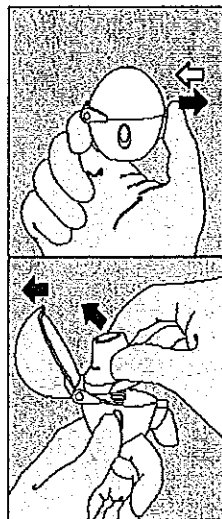
How to Use SPIRIVA through the HandiHaler® Inhalation Device:



1. Become familiar with the HandiHaler® device.



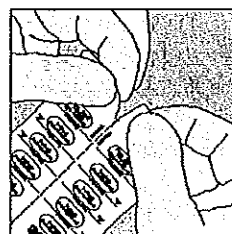
- 1. Dust cap
- 2. Mouthpiece
- 3. Mouthpiece ridge
- 4. Base
- 5. Piercing button
- 6. Centre chamber
- 7. Air intake vents



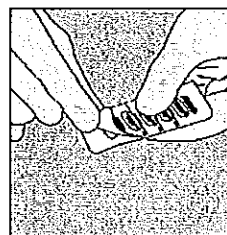
2. To release the dust cap, press the green piercing button completely in and let go.

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

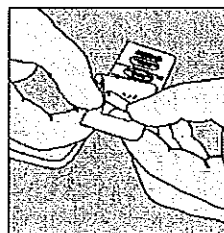
4. Blister Handling:



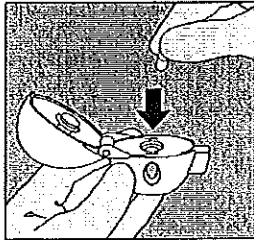
4A. The blister card contains two blister strips joined along a perforated line. Prior to removing the first capsule from the blister card, separate the blister strips by tearing along the perforation.



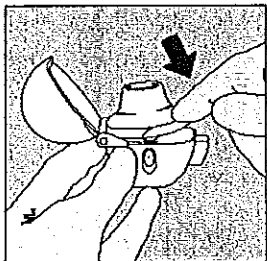
4B. Immediately before use, peel the aluminum back foil until one capsule is fully visible. After opening a strip, the in-use shelf life of the remaining capsules in the strip is 5 days.



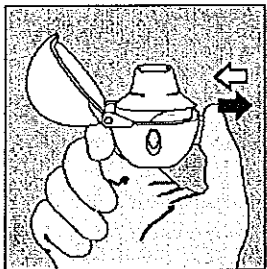
4C. Remove one SPIRIVA capsule from the blister. Do not expose more than one capsule. If more than one capsule is exposed, you should discard the exposed unused capsules. Do not store the capsule in the HandiHaler® device.



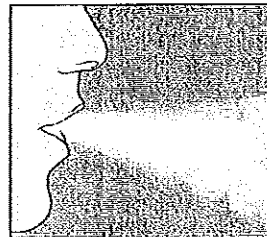
5. Place the capsule in the centre chamber. It does not matter which end of the capsule is placed in the chamber.



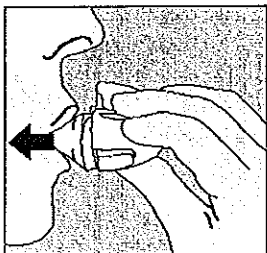
6. Close the mouthpiece firmly until you hear a click, leaving the dust cap open.



7. Hold the HandiHaler® 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.



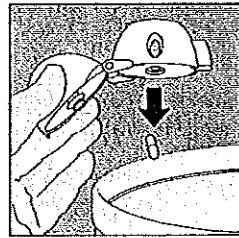
8. If you feel that your chest is congested with mucus, try to cough to clear your lungs before you inhale SPIRIVA. Breathe out completely. **Important: Do not breathe into the mouthpiece at any time.**



9. Hold the HandiHaler® by the grey base. Do not block the air intake vents. Raise the HandiHaler® 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.

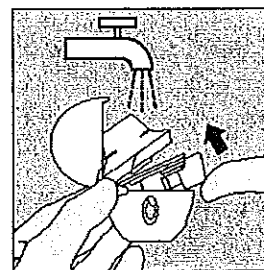
Breathe in until your lungs are full; then hold your breath as long as comfortable (try counting to 10) and at the same time take the HandiHaler® out of your mouth. Resume normal breathing.

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® 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 health care 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You should be aware that prescription medicines carry some risks and that all possible risks may not be known at this stage. Discuss with your doctor the risks of taking SPIRIVA against the expected benefits.

The most commonly reported undesirable effect of SPIRIVA is dry mouth, usually mild.

Less commonly (Uncommon) reported side effects of SPIRIVA are: dizziness, blurred vision, irregular heart beat, inflammation of the throat, constipation, cough, inflammation of the mouth, hoarseness, heart burn, rash, difficulties passing urine, painful urination.

Rare reported side effects of SPIRIVA include: difficulty in sleeping, seeing halos around lights or coloured images in association with red eyes, increase of the measured eye pressure, faster heart beat, feeling your heartbeat, tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation, nosebleed, inflammation of the larynx, inflammation of the sinuses, blockage of intestines or absence of bowel movements, inflammation of the gums, inflammation of the tongue, fungal infections of the oral cavity and throat, difficulties swallowing, hypersensitivity, including immediate reactions, nettle rash, itching, infections of the urinary tract.

Additional possible side effects associated with SPIRIVA include: depletion of body water, serious allergic reaction which causes swelling of the face or throat, infections or ulcerations of the skin, dryness of the skin, swelling of joints.

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

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

This is not a complete list of side effects. For any unexpected effects while taking SPIRIVA, contact your doctor or pharmacist immediately, so that these effects may be properly addressed.

If you experience dry mouth or bad taste, sucking on a sour candy or rinsing your mouth may help.

Check with your doctor if the dry mouth or bad taste persists or if you experience constipation.

If you do not get the expected relief from your treatment, you should contact your doctor.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	Persistent dry mouth, bad taste		✓	
Uncommon	Constipation		✓	
	Fast or irregular heart beat			✓
	Blurred vision or pain in the eyes			✓
	Difficult or painful urination			✓
	Skin rash/hives			✓
Rare	Tightness of the chest associated with coughing, wheezing, or breathlessness immediately after inhalation (bronchospasm)			✓
	Serious allergic reaction which causes swelling of the mouth and face or throat			✓
	Difficulty in swallowing			✓
Not Known	Suspected skin infection			✓
	Swelling of joints			✓

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

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 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

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 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, 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-ingelheim.ca>
or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 4633 (Medical Information)

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

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.
Last revised: June 29, 2010

Distributed by:
Boehringer Ingelheim (Canada) Ltd.
Burlington, ON, Canada

Co-promoted with:
Pfizer Canada Inc.
Kirkland, Quebec