

## New Zealand Consumer Medicine Information

### **SPIRIVA<sup>®</sup>**

**Powder for Inhalation**

***Tiotropium bromide***

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#### **What is in this leaflet**

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This leaflet answers some common questions about SPIRIVA capsules. It does not contain all available information. Nor does it take the place of talking to your doctor or pharmacist. Keep this information with your capsules. You may need to read it again later.

#### ***To find out more about SPIRIVA***

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using SPIRIVA.

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#### **What SPIRIVA is used for**

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SPIRIVA is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD). This helps to improve your condition and to prevent exacerbations (periodic worsening of symptoms) from occurring. SPIRIVA improves breathing by relaxing the breathing tubes or air passages that carry air to and from the lungs. It begins to act within 30 minutes after use and the effect should last a full day.

SPIRIVA contains the active ingredient tiotropium bromide. This medicine is known as an anticholinergic medicine.

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#### **Before you use SPIRIVA**

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##### ***When not to use SPIRIVA***

Only use SPIRIVA if it has been prescribed for you by a doctor. Never give it to someone else even if their symptoms seem to be the same as yours.

Do not use SPIRIVA if you are allergic to it or to any of the ingredients. These ingredients are listed in full at the end of this leaflet (see ingredients). In some cases you should not use SPIRIVA if you are allergic to certain other medicines. You must tell your doctor if you are allergic to atropine or any other anticholinergic medicines. If you are uncertain as to whether you have these allergies you should raise your concerns with your doctor.

You should never use SPIRIVA after the EXPIRY DATE on the blister strips or carton.

##### ***Before you start to use SPIRIVA***

It is essential that your doctor knows your medical history before prescribing SPIRIVA. Before using SPIRIVA, you must tell your doctor if you have, or have had, any of the following conditions:

- high pressure in the eye (glaucoma)

- kidney problems
- problems with your prostate gland
- problems with passing urine

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Before taking SPIRIVA you must tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription. In particular you must tell your doctor if you are taking other anticholinergic medicines such as ipratropium.

### ***Pregnancy***

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. SPIRIVA is not generally recommended for use in pregnant women, unless the benefits of treatment outweigh the risk to the unborn baby.

### ***Breastfeeding***

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. It is not known whether SPIRIVA passes into breast milk in breastfeeding women. Your doctor will discuss the risks and benefits of using SPIRIVA if you intend to breastfeed.

### ***Children***

SPIRIVA should not be used in children.

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## **Using SPIRIVA**

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### ***How to use SPIRIVA***

The powder in the capsules must only be inhaled using the HandiHaler device. Use each strip of 5 capsules within 5 days of first opening the strip.

Please read the Directions for Use at the end of this leaflet for instructions on how to use SPIRIVA capsules with the HandiHaler device. Follow the Directions for Use carefully. Using the HandiHaler device, pierce the capsule only once. If you pierce it more often, the capsule may break and pieces of gelatin from the capsule shell, small enough to pass the sieve, may be inhaled into your mouth or throat. Gelatin is not harmful and small particles swallowed or inhaled will be digested or absorbed and are not expected to cause undesirable effects.

If you have any problems inhaling SPIRIVA using the HandiHaler device ask your doctor or pharmacist for advice.

Never allow SPIRIVA powder to come into contact with your eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes.

### ***Recommended Dose***

The recommended dose for adults is 1 capsule to be inhaled, once a day.

### ***If you forget to inhale a dose***

It is important to use SPIRIVA as directed. If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time. Do not take a double dose to make up for the dose that you missed.

### ***How long to take SPIRIVA***

SPIRIVA helps control your condition, but does not cure it. Therefore you must use SPIRIVA every day. Continue using the medicine for as long as your doctor or pharmacist tells you. Do not stop using it unless your doctor or pharmacist tells you to – even if you feel better.

### ***Overdose***

Seek medical advice if you have used more than the recommended or prescribed dose of SPIRIVA and you experience signs of overdose as listed below. Advice can be provided by a doctor, pharmacist or Poisons Information Centre (phone 0800 764 766). Signs of overdose may include fast or irregular heart beat, blurred vision, nausea, stomach pain, dry mouth, constipation and difficulty passing urine.

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## **While you are using SPIRIVA**

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### ***Things you must do***

It is very important to follow the Directions for Use carefully and avoid contact of the powder with the eyes. Contact your doctor immediately if you experience eye pain or discomfort, or any disturbances with your sight (blurred vision, visual halos or coloured images) during or after using SPIRIVA. This is because there have been isolated reports of narrow-angle glaucoma with the use of SPIRIVA. If your breathing becomes more difficult while you are using SPIRIVA, tell your doctor immediately.

If you are a smoker, your doctor or pharmacist can advise you on the steps to take to quit smoking.

Tell your doctor or pharmacist if you begin taking any other medicine while you are using SPIRIVA. This applies to all medicines obtained with or without a doctor's prescription.

### ***Effects on ability to drive or operate machinery***

Be careful when driving or operating machinery until you know how SPIRIVA affects you. SPIRIVA may cause dizziness or blurred vision in some people. Make sure you know how you react to SPIRIVA before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

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## **Side effects**

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You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of you taking SPIRIVA against the benefits they expect it will have for you. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

The more frequently reported side effects of SPIRIVA are:

- dry mouth

- cough
- fast heart beat
- blurred vision
- high pressure in the eye (glaucoma)

Less frequently reported side effects of SPIRIVA include:

- constipation
- difficulty in passing urine
- pain while passing urine, increased need and frequency in passing urine
- itching, skin rash or allergic reactions (swollen tongue and lips, mouth ulcers and rash on the face)
- a change in heart rate
- heartburn
- oral thrush
- hoarse voice
- nose bleeds
- trouble sleeping

As with other inhaled medicines, a worsening of breathing problems (induced by the inhalation process) may occur. Tell your doctor as soon as possible if you experience any side effects during or after using SPIRIVA, so that these may be properly assessed. In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after using SPIRIVA.

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## After using SPIRIVA

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### ***Care and cleaning***

Follow the instructions under the heading Directions for Use at the end of this leaflet.

### ***Storage***

SPIRIVA should be kept in a cool, dry place where the temperature stays below 25°C. Do not store SPIRIVA in the bathroom or near the sink. Do not leave SPIRIVA in the car or on window sills. Heat and dampness can destroy the medicine. Do not store SPIRIVA in the freezer.

Keep your SPIRIVA capsules where children cannot reach them.

### ***Disposal***

If your doctor tells you that you will not be needing SPIRIVA anymore, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

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## Product Description

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### ***What SPIRIVA is***

SPIRIVA is the brand name of your medicine. It comes as a powder inside a capsule. You must use the HandiHaler device in order to inhale powder from the capsule.

SPIRIVA capsules contain a white powder. SPIRIVA capsules are light green with the product code "TI 01" and the Boehringer Ingelheim logo printed in black ink on the capsules. **SPIRIVA capsules contain only a small amount of powder, which**

**means that the capsule is only partially filled. The amount of powder in each capsule is equivalent in size to the tip of a matchstick.**

Each pack contains 30 capsules.

The HandiHaler device is available separately from your pharmacist.

### ***Ingredients***

Each capsule of SPIRIVA contains tiotropium 18 micrograms (equivalent to tiotropium bromide monohydrate 22.5 micrograms). SPIRIVA also contains 5.5 milligrams of lactose (which contains milk protein).

### ***Distributor***

SPIRIVA is supplied in New Zealand by:  
BOEHRINGER INGELHEIM (N.Z.) LIMITED  
PO Box 76-216  
Manukau City  
Auckland  
Ph 0800 802461

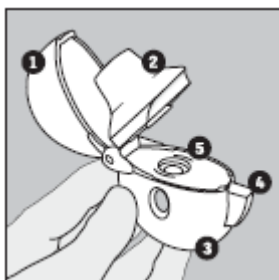
This leaflet was prepared on 6 August 2010

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## HandiHaler®

### *How do you take your dose of SPIRIVA using the HandiHaler?*

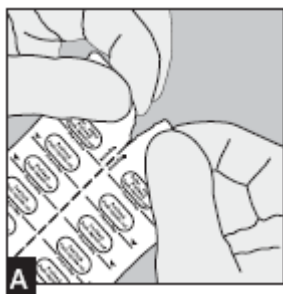
Taking your dose of SPIRIVA requires four main steps: Open the blister and the HandiHaler device, insert the SPIRIVA capsule, press the HandiHaler button, and inhale your medication.



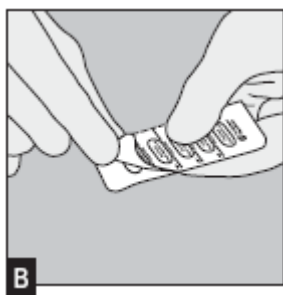
Become familiar with the components of the HandiHaler inhalation device:

1. dust cap
2. mouthpiece
3. base
4. piercing button
5. centre chamber

### *Removing the SPIRIVA capsule from the blister*



SPIRIVA capsules are packaged in a blister card. Each blister card consists of two blister strips, each containing 5 capsules and joined along a perforated line. Prior to removing the first capsule from the blister card, separate the blister strips by tearing along the perforation. (Figure A)



The blister should be carefully opened to expose only one capsule at a time.

Immediately before you are ready to use your dose of SPIRIVA, peel back the aluminium foil using the tab at the rounded edge until one capsule is fully visible. The foil lidding should only be peeled back as far as the STOP line printed on the blister foil to prevent exposure of more than one capsule. (Figure B) Turn the blister strip upside down and tip the capsule out, tapping the back of the blister pack, if necessary.

**DO NOT CUT THE FOIL OR USE SHARP INSTRUMENTS TO REMOVE THE CAPSULE FROM THE BLISTER.**

Capsules should always be stored in the sealed blisters and only removed immediately before use. The medicine should be used immediately after the packaging over an individual capsule is opened, or else its effectiveness may be reduced. If additional capsules are inadvertently exposed to air, they should not be used and should be discarded.

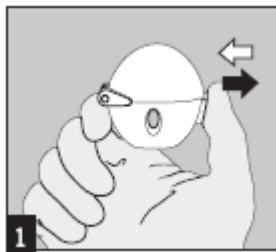
Do not store capsules in the HandiHaler.

### ***Directions for Use***

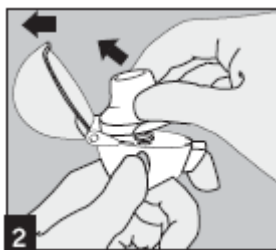
The HandiHaler enables you to inhale the medicine contained in the SPIRIVA capsule that your doctor has prescribed for your breathing problems.

Remember to carefully follow your doctor's instructions for using SPIRIVA.

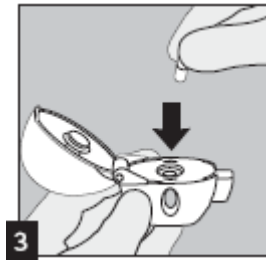
The HandiHaler is especially designed for SPIRIVA. It must not be used to take any other medication. Your HandiHaler can be used for up to twelve months to take your medication. You will need to replace your HandiHaler every twelve months.



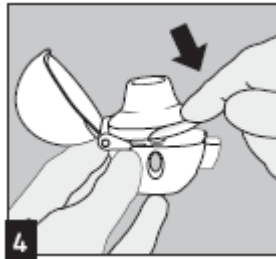
To release the dust cap press the piercing button completely in and let go.



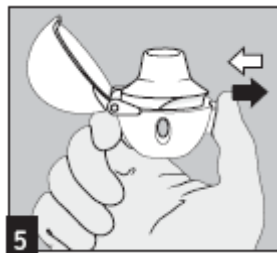
**OPEN:** Open the dust cap by pulling it upwards. Then open the mouthpiece by pulling it upwards.



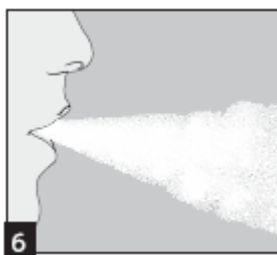
**INSERT:** Place the capsule in the centre chamber. It does not matter which end of the capsule is placed in the chamber.



Close the mouthpiece firmly until you hear a click, leaving the dust cap open. Check to see that the mouthpiece is completely closed. Be sure that the mouthpiece sits firmly against the base so that there is no gap between the mouthpiece and the base.

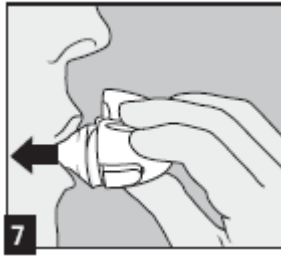


**PRESS:** Hold the HandiHaler with the mouthpiece upwards and press the piercing button completely in only once until it is flush against the base, and release. This makes holes in the capsule and allows the medication to be released when you breathe in.



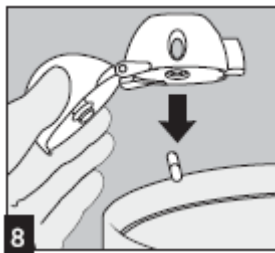
Breathe out completely.

**Important:** Do not breathe (exhale) into the HandiHaler mouthpiece at any time.

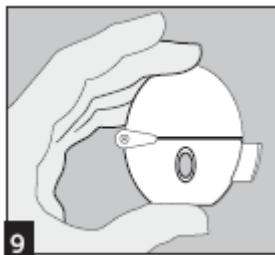


**INHALE:** Raise the HandiHaler to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position and breathe in slowly and deeply but at a rate sufficient to hear or feel the capsule vibrate. Breathe in until your lungs are full; then hold your breath as long as is comfortable and at the same time take the HandiHaler out of your mouth. Resume normal breathing.

To ensure you get the full dose of SPIRIVA, you must repeat steps 6 and 7 once again. If you do not hear or feel the capsule vibrate, tap the HandiHaler gently on a table, holding it in an upright position. Check to see that the mouthpiece is completely closed. Then breathe in again - slowly and deeply. If you still do not hear or feel the capsule vibrate after repeating the above steps please consult your doctor or pharmacist to ensure that you are using the HandiHaler correctly.

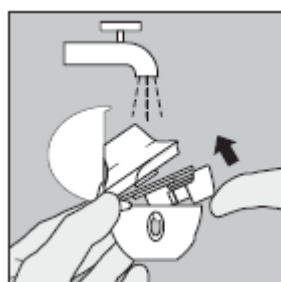


After you have finished taking your daily dose of SPIRIVA, open the mouthpiece again. Tip out the used capsule and discard.



Close the mouthpiece and dust cap for storage of your HandiHaler device.

### ***Cleaning your HandiHaler***



Clean the HandiHaler once a month. Open the dust cap and mouthpiece. Then open the base by lifting the piercing button. Rinse the complete inhaler with warm water to remove any powder. Dry the HandiHaler thoroughly by tipping excess 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 use it and it will be ready for your next dose.

If needed, the outside of the mouthpiece may be cleaned with a moist, but not wet, tissue.