



Patient's Instructions For Use

Spiriva® HandiHaler® (tiotropium bromide inhalation powder)

FOR ORAL INHALATION ONLY

Read all instructions before use.

This leaflet provides summary information about Spiriva capsules and the HandiHaler inhalation device. Before you start to take Spiriva or use the HandiHaler, read this leaflet carefully and keep it for future use. You should read the leaflet that comes with your prescription every time you refill it because there may be new information.

For more information, ask your health-care provider or pharmacist.

What should you know about Spiriva and the HandiHaler?

Each Spiriva capsule contains a dry powder blend of active drug (18 mcg tiotropium) and lactose monohydrate as the carrier. The dry powder in the capsule is inhaled from the HandiHaler inhalation device. Spiriva capsules contain only a small amount of powder and as a result the capsule is only partially filled. When disposing of the capsule, you may notice that a tiny amount of this powder is left in the capsule. This is normal.

Spiriva is a once daily maintenance bronchodilator medicine that opens narrowed airways and helps keep them open for 24 hours. Spiriva HandiHaler should not be used for immediate relief of breathing problems, i.e., as a rescue medication.

SPIRIVA CAPSULES ARE INTENDED FOR ORAL INHALATION ONLY AND ARE TO BE USED ONLY WITH THE HANDIHALER INHALATION DEVICE.

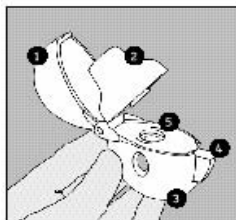
SPIRIVA CAPSULES SHOULD NOT BE SWALLOWED.

The HandiHaler is an inhalation device that has been specially designed for use with Spiriva capsules. It must not be used to take any other medication.

Care must be taken not to allow the powder to enter into the eyes. If symptoms of eye pain, eye discomfort, blurred vision, visual halos, or colored images in association with red eyes occur, consult a physician immediately.

40 **How do you take your dose of Spiriva using the HandiHaler?**

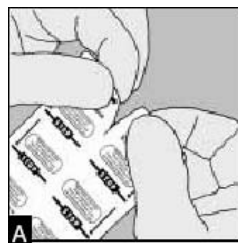
Taking your dose of Spiriva, requires four main steps: Open the blister and the HandiHaler device, insert the Spiriva capsule, press the HandiHaler button, and inhale your medication. (See below for details.)



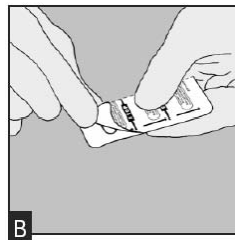
Become familiar with the components of the HandiHaler inhalation device:

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

Removing the Spiriva capsule from the blister.



A) Spiriva capsules are packaged in a blister card. Each blister card consists of two blister strips, each containing 3 capsules and joined along a perforated-cut line. Prior to removing the first capsule from the blister card, separate the blister strips by tearing along the perforation. (Figure A)



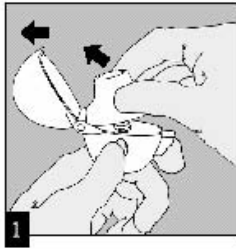
B) The blister should be carefully opened to expose only one capsule at a time. Immediately before you are ready to use your dose of Spiriva, peel back the aluminum foil using the tab until one capsule is fully visible. The foil lidding should only be peeled back as far as the **STOP** line printed on the blister foil to prevent exposure of more than one capsule. (Figure B). After using the first capsule, the 2 remaining capsules should be used over the next 2 consecutive days.

Capsules should always be stored in the sealed blisters and only removed immediately before use. The drug should be used immediately after the packaging over an individual capsule is opened, or else its effectiveness may be reduced.

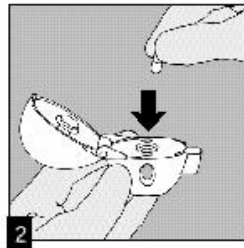
If additional capsules are inadvertently exposed to air, they should not be used and should be discarded.

Do not store capsules in the HandiHaler device.

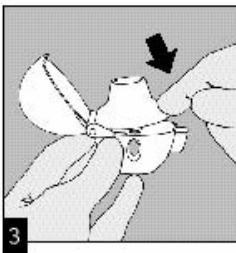
Opening the HandiHaler device and inserting the Spiriva capsule.



1) OPEN: Open the dust cap by pulling it upwards. Then open the mouthpiece. (Figure 1)



2) INSERT: Place the capsule in the center chamber. It does not matter which end of the capsule is placed in the chamber. (Figure 2)

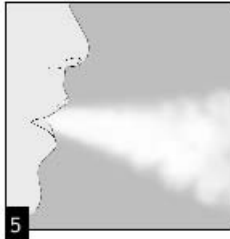


3) Close the mouthpiece **firmly until you hear a click**, leaving the dust cap open. (Figure 3)

Taking your dose of Spiriva.

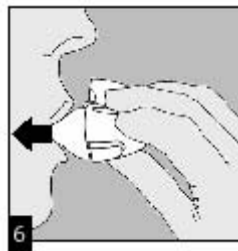


4) PRESS: Hold the HandiHaler device with the mouthpiece upwards and press the piercing button completely in once, and release. This makes holes in the capsule and allows the medication to be released when you breathe in. (Figure 4)



5) Breathe out completely. (Figure 5)

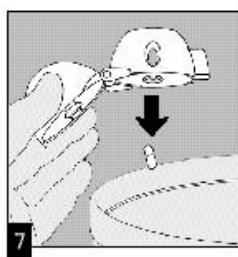
Important: Do not breathe (exhale) into the HandiHaler mouthpiece at any time.



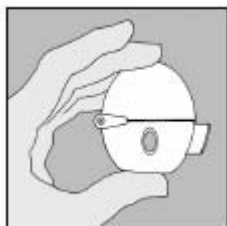
6) INHALE: Raise the HandiHaler device to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position and breathe in slowly and deeply but at a rate **sufficient to hear the capsule vibrate**. Breathe in until your lungs are full; then hold your breath as long as is comfortable and at the same time take the HandiHaler device out of your mouth. Resume normal breathing. (Figure 6).

To ensure you get the full dose of Spiriva, you must repeat steps 5 and 6 once again.

If you do not hear the capsule vibrate after repeating the above steps please consult your physician.

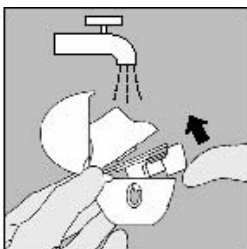


7) After you have finished taking your daily dose of Spiriva, open the mouthpiece again. Tip out the used capsule and discard. (Figure 7)



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

41 **When and how should you clean your HandiHaler Device?**



Normally, during a one-month period of use, the HandiHaler device does not need to be cleaned. However, if cleaning is needed the HandiHaler device can be cleaned as described below:

Open the dust cap and mouthpiece. Open the base by lifting the piercing button. Rinse the complete inhaler with warm water to remove any powder. Do not use cleaning agents or detergents.

Dry the HandiHaler device thoroughly by tipping the 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.** Do not use the HandiHaler device when it is wet.

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

The HandiHaler device should not be placed in the dishwasher for cleaning.

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43 **Where should you store Spiriva capsules and the HandiHaler Device?**

44 **Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)** [see USP Controlled
45 Room Temperature].

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47 The capsules should not be exposed to extreme temperature or moisture. Do not store
48 capsules in the HandiHaler.

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50 As with all prescription medications, keep this out of the reach of children.

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52 **Tell your doctor before you use Spiriva HandiHaler:**

53 if you may be pregnant or wish to become pregnant;

54 if you are a breastfeeding mother;

55 if you are taking any medications including eye drops, this includes those you can buy
56 without a prescription;

57 if you have any other medical problems such as difficulty urinating or an enlarged
58 prostate;

59 if you are allergic to any medications.

60

61 **USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY**
62 **YOUR PHYSICIAN.**

63

Boehringer Ingelheim Pharmaceuticals, Inc.
Spiriva® HandiHaler® (tiotropium bromide inhalation powder)
Draft Patient Instructions for Use

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64 Manufactured by:
65 Boehringer Ingelheim Pharma GmbH & Co. KG
66 Ingelheim, Germany

67
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69 Boehringer Ingelheim Pharmaceuticals, Inc.
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81
82 Tiotropium bromide is covered by U.S. Patent No. 5,610,163 with other Patents Pending. The
83 HandiHaler inhalation device is covered by U.S. Design Patent No. 355,029.

84
85 Date
86 Identification number