

Spiriva®
HandiHaler®
(tiotropium bromide
inhalation powder)

 **Boehringer
Ingelheim**



Do Not Swallow Capsules.

For Use With HandiHaler Only.

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 capsules with 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 healthcare provider or pharmacist.

What should you know about SPIRIVA Capsules and the HandiHaler?

Do Not Swallow Capsules. Capsules must be used only with the HandiHaler device. 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 which makes the capsule appear almost empty.** When disposing of the capsule, you may notice that a dusting of this powder is left in the capsule. This is normal.

SPIRIVA HandiHaler 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.

Tell your doctor before you use SPIRIVA HandiHaler:

- if you may be pregnant or wish to become pregnant;
- if you are a breastfeeding mother;
- if you are taking any medications including eye drops, this includes those you can buy without a prescription;
- if you have any other medical problems such as difficulty urinating or an enlarged prostate;
- if you are allergic to any medications.

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

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.

Becoming familiar with SPIRIVA HandiHaler:

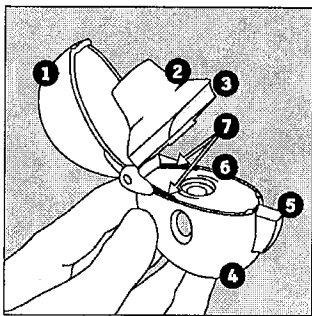


Figure A

Remove the HandiHaler inhalation device from the pouch and become familiar with its components. (Figure A)

1. dust cap
2. mouthpiece
3. mouthpiece ridge
4. base
5. green piercing button
6. center chamber
7. air intake vents

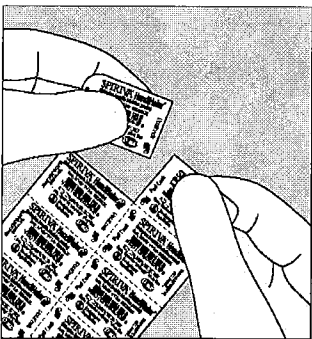


Figure B

Each SPIRIVA capsule is packaged in a blister. Each blister can be separated from the blister card by tearing along the perforation. (Figure B)

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

Taking your dose of SPIRIVA, requires four main steps:

1. **OPEN** the HandiHaler device and the blister
2. **INSERT** the SPIRIVA capsule
3. **PRESS** the green piercing button
4. **INHALE** your medication

(See below for details)

Opening the HandiHaler device:

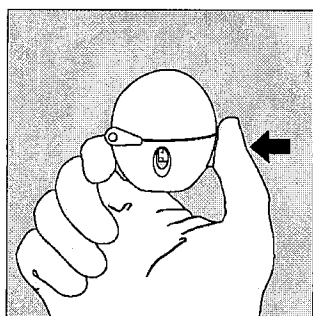


Figure 1

OPEN the dust cap by pressing the green piercing button. (Figure 1)



Figure 2

Pull the dust cap upwards to expose the mouthpiece. (Figure 2)



Figure 3

Open the mouthpiece by pulling the mouthpiece ridge upwards. (Figure 3)

Removing a SPIRIVA capsule:

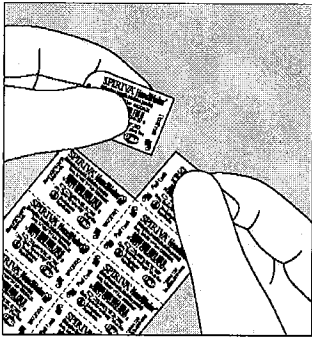


Figure 4

Prior to removing a SPIRIVA capsule from the blister, separate one of the blisters from the blister card by tearing along the perforation. (Figure 4)

Do not swallow Spiriva Capsules.

Capsules should always be stored in the sealed blisters and only removed immediately before use. Do not store capsules in the HandiHaler device. The drug should be used immediately after the packaging of an individual capsule is opened, or else its effectiveness may be reduced.

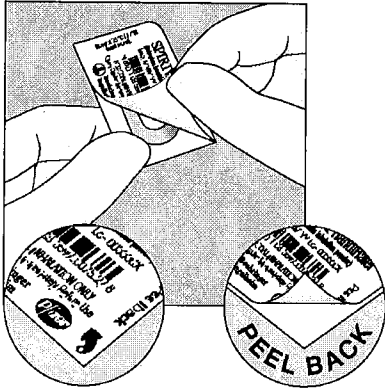


Figure 5

Immediately before you are ready to use your dose of SPIRIVA:

Bend back and forth one of the corners that has an arrow and with your finger separate the aluminum foil layers. Then carefully peel back the printed foil until the capsule is fully visible. (Figure 5)

Turn the blister upside down and tip the capsule out, tapping the back of the blister, if necessary.

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

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

Inserting the SPIRIVA capsule into the HandiHaler:

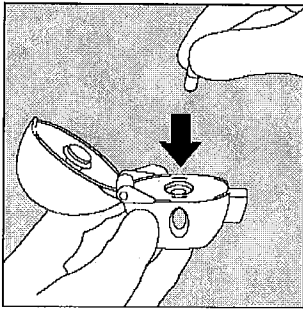


Figure 6

INSERT the capsule in the center chamber of the HandiHaler device. It does not matter which end of the capsule is placed in the chamber. (Figure 6)

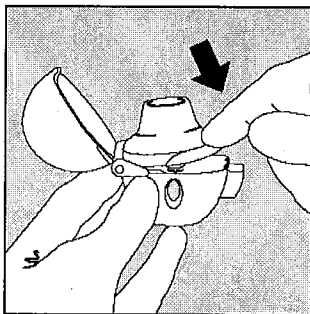


Figure 7

Close the mouthpiece **firmly until you hear a click**, leaving the dust cap open. (Figure 7)

Be sure that the mouthpiece sits firmly against the gray base.

Taking your dose of SPIRIVA:

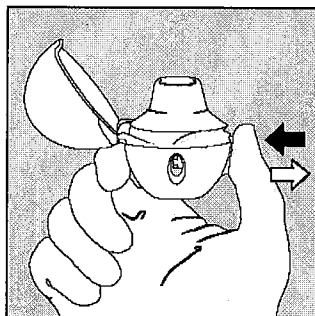


Figure 8

Hold the HandiHaler device with the mouthpiece upwards.

PRESS the green piercing button 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. (Figure 8)

DO NOT PRESS THE GREEN PIERCING BUTTON MORE THAN ONE TIME.

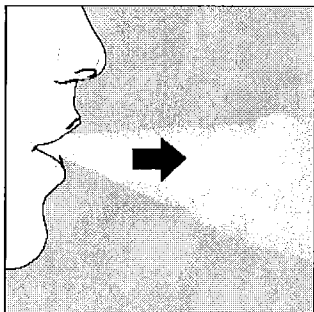


Figure 9

Breathe out completely. (Figure 9)

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

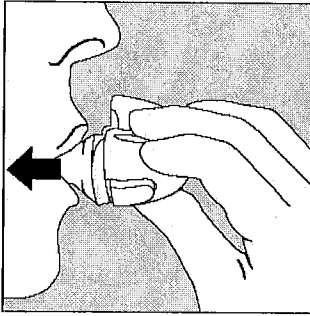


Figure 10

INHALE

- Hold the HandiHaler by the gray base. Do not block the air intake vents.
- Raise the HandiHaler device to your mouth and close your lips tightly around the mouthpiece.
- **Keep your head in an upright position. The HandiHaler should be in a horizontal position.** (Figure 10)
- Breathe in **slowly and deeply** but at a rate **sufficient to hear or feel the capsule vibrate.**
- Breathe in until your lungs are full.
- Hold your breath as long as is comfortable and at the same time take the HandiHaler device out of your mouth. Resume normal breathing.

To ensure you get the full dose of SPIRIVA, you must again breathe out completely and inhale once again as previously described (Figure 10).

DO NOT PRESS THE GREEN PIERCING BUTTON AGAIN.

If you do not hear or feel the capsule vibrate, **Do Not Press The Green Piercing Button Again** but instead 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 physician.

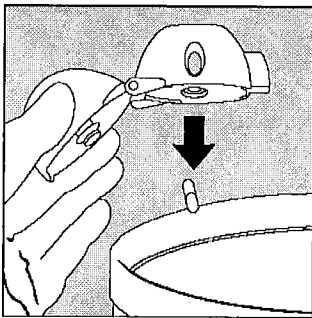


Figure 11

After you have finished taking your daily dose of SPIRIVA, open the mouthpiece again. Tip out the used capsule and discard. (Figure 11)

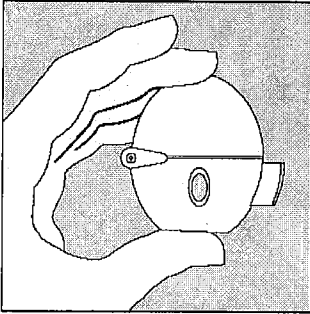


Figure 12

Close the mouthpiece and dust cap for storage of your HandiHaler device. (Figure 12)

Do not store the used or unused capsules in the HandiHaler device.

When and how should you clean your HandiHaler Device?

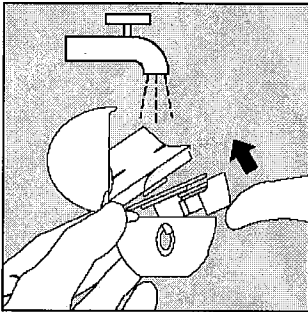


Figure 13

Clean the HandiHaler once a month. (Figure 13)

- Open the dust cap and mouthpiece.
- Open the base by lifting the green piercing button.
- Rinse the complete inhaler with warm water to remove any powder.
- Do not use cleaning agents or detergents.
- Do not place the HandiHaler in the dishwasher for cleaning.
- Dry the HandiHaler 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.

Where should you store SPIRIVA capsules and the HandiHaler Device?

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

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

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

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SPIRIVA® (tiotropium bromide inhalation powder) is covered by U.S. Patent Nos. RE38,912, RE39,820, 6,777,423, 6,908,928, and 7,070,800 with other patents pending. The HandiHaler® inhalation device is covered by U.S. Design Patent No. D355,029 with other patents pending.

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