

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL – Dublin 2.
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

5. How to store Spiriva Respimat

Keep out of the sight and reach of children.

Do not use Spiriva Respimat after the expiry date which is stated on the carton and on the inhaler label. The expiry date refers to the last day of the month. Spiriva Respimat inhaler should be discarded at the latest 3 months after first use (see Instructions for Use overleaf).

Do not freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Spiriva Respimat contains:

The active substance is tiotropium. The delivered dose is 2.5 microgram tiotropium per puff (2 puffs comprise one medicinal dose) and is equivalent to 3.124 microgram tiotropium bromide monohydrate. The delivered dose is the dose which is available for the patient after passing the mouthpiece.

The other ingredients are:
Benzalkonium chloride, disodium edetate, purified water, and hydrochloric acid 3.6% for pH adjustment.

What Spiriva Respimat looks like and contents of the pack

SPIRIVA RESPIMAT 2.5 microgram is composed of one cartridge with solution for inhalation and one Respimat inhaler. The cartridge has to be inserted into the inhaler before the first use.

Single Pack: 1 Respimat inhaler and
1 cartridge, providing 60 puffs (30 medicinal doses)

Manufactured by: Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, D-55216 Ingelheim am Rhein, Germany

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Spiriva Respimat 2.5microgram, Solution for inhalation – PPA: 1328/154/1

POM

Leaflet date: 19.02.2016

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Spiriva® Respimat® inhaler

How to use your Spiriva Respimat inhaler

This leaflet explains how to use and care for your Spiriva Respimat inhaler. **Please read and carefully follow these instructions.** See also section 3. How to take Spiriva Respimat on the other side of this leaflet.

The Spiriva Respimat inhaler releases medication slowly and gently, making it easy to inhale it into your lungs.

The Spiriva Respimat inhaler enables you to inhale the medicine contained in a cartridge. The full cartridge provides 60 puffs (30 medicinal doses). **You will need to use this inhaler only ONCE A DAY**, if possible at the same time of the day.

Each time you use it take TWO PUFFS.

There is enough medicine for 30 days when it is used according to the directions for use. In the box you will find the Spiriva Respimat inhaler and the Spiriva Respimat cartridge. Before the Spiriva Respimat inhaler is used for the first time, the cartridge provided must be inserted.



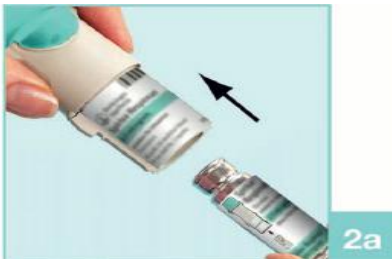
Spiriva Respimat inhaler and the Spiriva Respimat cartridge

1) Inserting the cartridge

The following steps 1– 6 are necessary before first use:



1. With the green cap (A) closed, press the safety catch (E) while pulling off the clear base (G).



2. Take the cartridge (H) out of the box. Push the **narrow** end of the cartridge into the inhaler until it **clicks** into place. The cartridge should be pushed **firmly** against a firm surface to ensure that it has gone all the way in (2b). The cartilage will not be flush with the inhaler, you will still see the silver ring of the lower end of the cartilage. Do not remove the cartridge once it has been inserted into the inhaler.



3. Replace the clear base (G). Do not remove the clear base again.

2) To prepare the Spiriva Respimat inhaler for first-time use



4. Hold the Spiriva Respimat inhaler upright, with the green cap (A) closed. Turn the base (G) in the direction of the black arrows on the label until it clicks (half a turn)



5. Open the green cap (A) until it snaps fully open.



6. Point the Spiriva Respimat inhaler towards the ground. Press the dose release button (D). Close the green cap (A).

Repeat steps 4, 5 and 6 until a cloud is visible. Then repeat steps 4, 5 and 6 three more times to ensure the inhaler is prepared for use. Your Spiriva Respimat inhaler is now ready to use.

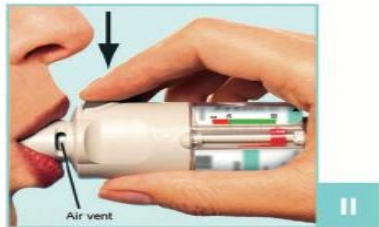
These steps will not affect the number of doses available. After preparation your Spiriva Respimat inhaler will be able to deliver your 60 puffs (30 medicinal doses).

Daily use of your Spiriva Respimat inhaler

You will need to use this inhaler **ONLY ONCE A DAY**. Each time you use it take **TWO PUFFS**.



- I. Hold the Spiriva Respimat inhaler upright, with the green cap (A) closed, to avoid accidental release of the dose. Turn the base (G) in the direction of the black arrows on the label until it clicks (half a turn).



- II. Open the green cap (A) until it snaps fully open. Breathe out slowly and fully, and then close your lips around the end of the mouthpiece without covering the air vents (C). Point your Spiriva Respimat inhaler to the back of your throat. While taking in a slow, deep breath through your mouth, press the dose release button (D) and continue to breathe in slowly for as long as you can. Hold your breath for 10 seconds or for as long as comfortable.

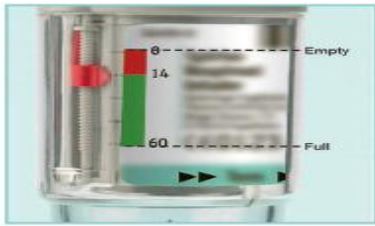
- III. Repeat steps I and II so that you get the full dose.

You will need to use this inhaler only ONCE A DAY.

Close the green cap until you use your Spiriva Respimat inhaler again.

If Spiriva Respimat inhaler has not been used for more than 7 days release one puff towards the ground. If Spiriva Respimat inhaler has not been used for more than 21 days repeat steps 4 to 6 until a cloud is visible. Then repeat steps 4 to 6 three more times.

When to get a new Spiriva Respimat inhaler



The Spiriva Respimat inhaler contains 60 puffs (30 medicinal doses). The dose indicator shows approximately how much medication is left. When the pointer enters the red area of the scale, there is, approximately, medication for 7 days left (14 puffs). This is when you need to get a new Spiriva Respimat inhaler prescription.

Once the dose indicator has reached the end of the red scale (i.e. all 30 doses have been used), the Spiriva Respimat inhaler locks automatically – no more doses can be released. At this point, the base cannot be turned any further.

At the latest, three months after use the Spiriva Respimat inhaler should be discarded even if not all medication has been used.

What if

What if...	Reason	What to do
I can't turn the base easily.	a) The Spiriva Respimat inhaler is already prepared and ready to use. b) The Spiriva Respimat inhaler is locked after 60 puffs (30 medicinal doses).	a) The Spiriva Respimat inhaler can be used as it is. b) Prepare and use your new Spiriva Respimat inhaler.
The cap is fully pulled off and apart from the inhaler.	While opening the cap it was pulled too hard.	The cap can easily be attached again.
I can't press the dose release button.	The clear base has not turned.	Turn the clear base until it clicks . (half a turn)
The clear base springs back after I have turned it.	The clear base was not turned far enough.	Prepare the Spiriva Respimat inhaler for use by turning the clear base until it clicks . (half a turn)
I can turn the clear base past the point where it clicks.	Either the dose release button has been pressed, or the clear base has been turned too far.	With the green cap closed , turn the base until it clicks . (half a turn)

How to care for your inhaler

Clean the mouthpiece including the metal part inside the mouthpiece with a damp cloth or tissue only, at least once a week.

Any minor discolouration in the mouthpiece does not affect the performance of your Spiriva Respimat inhaler.

If necessary, wipe the outside of your Spiriva Respimat inhaler with a damp cloth.

Further information

The Spiriva Respimat inhaler must not be disassembled after inserting the cartridge and replacing the clear base.

Do not touch the piercing element inside the base.