

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

# Spiriva® Respimat® 2.5 microgram, Solution for Inhalation

tiotropium

Boehringer  
Ingelheim



**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What SPIRIVA RESPIMAT is and what it is used for
2. Before you take SPIRIVA RESPIMAT
3. How to take SPIRIVA RESPIMAT
4. Possible side effects
5. How to store SPIRIVA RESPIMAT
6. Further information

**1. WHAT SPIRIVA RESPIMAT IS AND WHAT IT IS USED FOR**

SPIRIVA RESPIMAT helps people who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a long-term lung disease that causes shortness of breath and coughing. The term COPD is associated with the conditions chronic bronchitis and emphysema. As COPD is a long-term disease you should take SPIRIVA RESPIMAT every day and not only when you have breathing problems or other symptoms of COPD.

SPIRIVA RESPIMAT is a long-acting bronchodilator that helps to open your airways and makes it easier to get air in and out of the lungs. Regular use of SPIRIVA RESPIMAT can also help you when you have ongoing shortness of breath related to your disease, and will help to minimise the effects of the disease on your everyday life. Daily use of SPIRIVA RESPIMAT will also help to prevent any sudden, short-term worsening of your COPD symptoms which may last for several days.

For correct dosing of SPIRIVA RESPIMAT please see section 3. How to take SPIRIVA RESPIMAT and the instructions for use provided on the other side of the leaflet.

**2. BEFORE YOU TAKE SPIRIVA RESPIMAT**

**Please read the following questions carefully.** If you can answer any of these questions with **‘Yes’** please discuss this with your doctor **before** taking SPIRIVA RESPIMAT

- are you allergic (hypersensitive) to tiotropium, atropine or similar drugs such as ipratropium or oxitropium?
- are you taking any other medicinal products containing ipratropium or oxitropium?
- are you pregnant, do you think you are pregnant, or are you breast-feeding?
- are you suffering from blurred vision, eye pain and/ or red eyes, prostate problems or have difficulty passing urine?
- do you have any kidney problems?

**Do not use SPIRIVA RESPIMAT**

- if you are allergic (hypersensitive) to tiotropium, its active ingredient or any of the other ingredients of SPIRIVA RESPIMAT
- if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium
- if you are under 18 years of age

**Take special care with SPIRIVA RESPIMAT**

When taking SPIRIVA RESPIMAT take care not to let any spray enter your eyes. This may result in eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes (i.e. narrow angle glaucoma). Eye symptoms may be accompanied by headache, nausea or vomiting. Wash your eyes in warm water, stop using tiotropium bromide and immediately consult your doctor for further advice.

If your breathing has got worse or if you experience rash, swelling or itching directly after using your inhaler, stop using it and tell your doctor immediately.

Dry mouth which has been observed with anti-cholinergic treatment may in the long term be associated with dental caries. Therefore, please remember to pay attention to oral hygiene.

SPIRIVA RESPIMAT is indicated for the maintenance treatment of your chronic obstructive pulmonary disease. **It should not be used to treat a sudden attack of breathlessness or wheezing.**

Make sure your prescriber knows if you have diseases of the heart, in particular conditions affecting your heartbeat (rhythm disorders). Rhythm disorders may include irregular heartbeat, too slow heart beat (bradycardia), or too fast heartbeat (tachycardia). This is important to decide if SPIRIVA RESPIMAT is the right medicine for you to take.

Do not take SPIRIVA RESPIMAT more frequently than once daily.

You should also contact your doctor if you feel that your breathing is worsening.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

In particular, please tell your doctor or pharmacist if you are taking/have taken anticholinergic drugs, e.g. ipratropium or oxitropium.

No interaction side effects have been reported when SPIRIVA RESPIMAT has been taken with other products used to treat COPD such as reliever inhalers, e.g. salbutamol, methylxanthines, theophylline and/or inhaled or oral steroids, e.g. prednisolone.

**Pregnancy and breast-feeding**

If you are pregnant or believe you are pregnant, or if you are breast-feeding, you should not use this medicine unless specifically recommended by your doctor.

Ask your doctor for advice before taking any medicine.

**Driving and using machines**

No studies on the effects and the ability to drive and use machines have been performed. In case dizziness or blurred vision occurs the ability to drive and use machinery may be influenced.

**3. HOW TO TAKE SPIRIVA RESPIMAT**

Always take SPIRIVA RESPIMAT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

SPIRIVA RESPIMAT is for inhalation use only.

The usual dose is: SPIRIVA RESPIMAT is effective for 24 hours so you will need to use SPIRIVA RESPIMAT only **ONCE A DAY**, if possible at the same time of the day. Each time you use it take **TWO PUFFS**.

As COPD is a long-term disease take SPIRIVA RESPIMAT every day and not only when you experience breathing problems. Do not take more than the recommended dose.

SPIRIVA RESPIMAT is not recommended for use in children and adolescents below 18 years due to lack of data on safety and efficacy.

Make sure that you know how to use your SPIRIVA RESPIMAT inhaler properly. The instructions for use of the SPIRIVA RESPIMAT inhaler are provided on the other side of this leaflet.

**If you take more SPIRIVA RESPIMAT than you should**

If you take more SPIRIVA RESPIMAT than two puffs in one day talk to your doctor immediately. You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, increased heart beat or blurred vision.

**If you forget to take SPIRIVA RESPIMAT**

If you forget to take your daily dose (**TWO PUFFS ONCE A DAY**), don't worry. Take it 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.

**If you stop taking SPIRIVA RESPIMAT**

Before you stop taking SPIRIVA RESPIMAT, you should talk to your doctor or your pharmacist. If you stop taking SPIRIVA RESPIMAT the signs and symptoms of COPD may worsen.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, SPIRIVA RESPIMAT can cause side effects, although not everybody gets them.

Evaluation of the side effects is based on the following frequencies:

Common:	affects less than 1 in 10, but more than 1 in 100 patients
Uncommon:	affects less than 1 in 100, but more than 1 in 1,000 patients
Rare:	affects less than 1 in 1,000, but more than 1 in 10,000 patients
Not known:	no frequency category could be determined from clinical trials

The side effects described below have been experienced by people taking this medicine and they are listed according to frequency as either common, uncommon, rare or not known.

**Common:**

- dry mouth: this is usually mild

**Uncommon:**

- dizziness
- headache
- irregular heart beat (atrial fibrillation, supraventricular tachycardia)
- feeling your heartbeat (palpitations)
- faster heart beat (tachycardia)
- cough
- nosebleed (epistaxis)
- inflammation of the throat (pharyngitis)
- hoarseness (dysphonia)
- constipation
- fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- difficulties swallowing (dysphagia)
- rash
- itching (pruritus)
- difficulties passing urine (urinary retention)
- painful urination (dysuria)

**Rare:**

- seeing halos around lights or coloured images in association with red eyes (glaucoma)
- increase of the measured eye pressure
- blurred vision
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- inflammation of the larynx (laryngitis)
- heart burn (gastrooesophageal reflux disease)
- dental caries
- inflammation of the gums (gingivitis)
- inflammation of the tongue (glossitis)
- inflammation of the mouth (stomatitis)
- serious allergic reaction which causes swelling of the mouth and face or throat (angioneurotic oedema)
- nettle rash (urticaria)
- infections or ulcerations of the skin
- dryness of the skin
- infections of the urinary tract

**Not known:**

- depletion of body water (dehydration)
- difficulty in sleeping (insomnia)
- inflammation in the sinuses (sinusitis)
- blockage of intestines or absence of bowel movements (intestinal obstruction, including ileus paralytic)
- feeling sick (nausea)
- hypersensitivity, including immediate reactions
- swelling of joint

Immediate allergic reactions such as rash, nettle rash (urticaria), swelling of the mouth and face or sudden difficulties in breathing (angioneurotic oedema) or other hypersensitivity reactions may occur after administration of SPIRIVA RESPIMAT. If this occurs, please consult your doctor immediately.

In addition, in common with all inhaled medicines, some patients may experience an unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (bronchospasm).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE SPIRIVA RESPIMAT**

Keep out of the reach and sight 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. FURTHER 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)
Double pack:	2 single packages, each containing 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)
Triple pack:	3 single packages, each containing 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)
Eight pack:	8 single packages, each containing 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The marketing authorisation holder for SPIRIVA RESPIMAT is:  
Boehringer Ingelheim International GmbH  
Binger Straße 173  
D-55216 Ingelheim am Rhein  
Germany

The manufacturer for SPIRIVA RESPIMAT is:  
Boehringer Ingelheim Pharma GmbH & Co. KG  
Binger Straße 173  
D-55216 Ingelheim am Rhein  
Germany

**This leaflet was last approved in 08/2010**

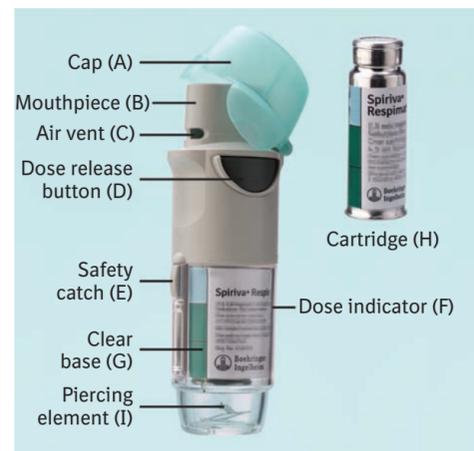
# Spiriva® Respimat® inhaler

## 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.

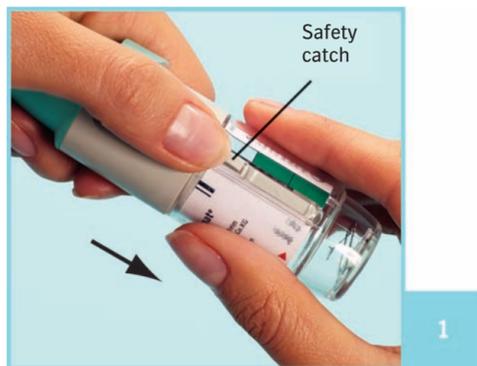
The SPIRIVA RESPIMAT inhaler enables you to inhale the medicine contained in a cartridge. The full cartridge provides 60 puffs (30 medicinal doses). **You will need to use this inhaler only ONCE A DAY**, if possible at the same time of the day. **Each time you use it take TWO PUFFS.** There is enough 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

## Inserting the cartridge and preparation for use

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

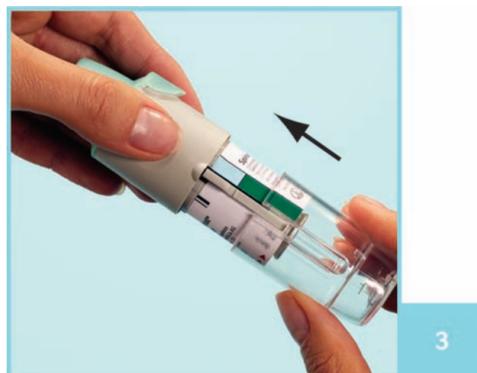


**1** With the green cap (A) closed, press the safety catch (E) and pull off the clear base (G).



**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 **gently** against a firm surface to ensure that it has gone all the way in (2b).

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.

## 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 red 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.

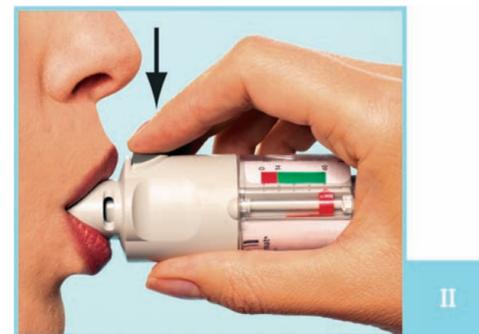
These steps will not affect the number of doses available. After preparation your SPIRIVA RESPIMAT inhaler will be able to deliver your 60 puffs (30 medicinal doses).

## Using the 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 dose. Turn the base (G) in the direction of the red 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 is empty and locks automatically. 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.
I can't press the dose release button.	The clear base has not been 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.

Boehringer Ingelheim Pharma GmbH & Co. KG  
D-55216 Ingelheim  
Germany