

Package leaflet: Information for the user

Spiriva® Respimat® 2.5 microgram, inhalation solution

tiotropium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Spiriva Respimat is and what it is used for
2. What you need to know before you take Spiriva Respimat
3. How to take Spiriva Respimat
4. Possible side effects
5. How to store Spiriva Respimat
6. Contents of the pack and other information

1. What Spiriva Respimat is and what it is used for

Spiriva Respimat helps people who have chronic obstructive pulmonary disease (COPD) or asthma 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. Asthma is a long-term disease characterised by airway inflammation and narrowing of the airways. As COPD and asthma are long-term diseases you should take Spiriva Respimat every day and not only when you have breathing problems or other symptoms. When used to treat asthma you should take Spiriva Respimat in addition to so-called inhaled corticosteroids and long-acting β_2 agonists.

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 on how to use the Respimat re-usable inhaler provided at the end of the leaflet.

2. What you need to know before you take Spiriva Respimat

Do not take Spiriva Respimat

- if you are allergic (hypersensitive) to tiotropium or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium.

Warnings and precautions

Talk to your doctor or pharmacist before taking Spiriva Respimat.

Talk to your doctor if you suffer from narrow angle glaucoma, prostate problems or have difficulty passing urine.

If you have problems with your kidneys, please consult your doctor.

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 or asthma. Do not take this medicine to treat a sudden attack of breathlessness or wheezing. Your doctor should have given you another inhaler ("rescue medication") for this. Please follow the instructions your doctor has given you.

If you have been prescribed Spiriva Respimat for your asthma it should be added on to your treatments that include an inhaled corticosteroid and long-acting β_2 agonists. Continue taking the inhaled corticosteroid as prescribed by your doctor, even if you feel better.

In case you have suffered from a myocardial infarction during the last 6 months or from any unstable or life threatening irregular heart beat or severe heart failure within the past year, please, inform your doctor. This is important to decide if Spiriva 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.

If you have cystic fibrosis, tell your doctor because Spiriva Respimat could make your cystic fibrosis symptoms worse.

Children and adolescents

Spiriva Respimat is not recommended for children under 6 years.

Other medicines and Spiriva Respimat

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 and asthma such as reliever inhalers (e.g. salbutamol), methylxanthines (e.g. theophylline), antihistamines, mucolytics (e.g. ambroxol), leukotriene modifiers (e.g. montelukast), cromones, anti-IgE treatment (e.g. omalizumab) and/or inhaled or oral steroids (e.g. budesonide, prednisolone).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not take this medicine unless specifically recommended by your doctor.

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.

Spiriva Respimat contains Benzalkonium chloride

This medicine contains 0.0011 mg benzalkonium chloride in each actuation.

Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

3. How to take Spiriva Respimat

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Spiriva Respimat is for inhalation use only.

The recommended dose for patients 6 years and older is:

Spiriva Respimat is effective for 24 hours so you will need to take 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 and asthma are long-term diseases take Spiriva Respimat every day and not only when you experience breathing problems. Do not take more than the recommended dose.

Make sure that you know how to use your Respimat re-usable inhaler properly. The instructions on how to use the Respimat re-usable inhaler are provided at the end of this leaflet, see 'Instructions on how to use the Respimat re-usable inhaler'.

Use in children and adolescents

Spiriva Respimat is not recommended for use in children below 6 years due to lack of data on safety and efficacy.

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 a dose (TWO PUFFS ONCE A DAY), 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 and asthma may worsen.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Not known:	frequency cannot be estimated from the available data

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.

Side effect	Frequency COPD	Frequency Asthma
Dry mouth	Common	Uncommon
Hoarseness (dysphonia)	Uncommon	Uncommon
Cough	Uncommon	Uncommon
Headache	Uncommon	Uncommon
Inflammation of the throat (pharyngitis)	Uncommon	Uncommon
Painful urination (dysuria)	Uncommon	Not known
Dizziness	Uncommon	Uncommon
Fungal infections of the oral cavity and throat (oropharyngeal candidiasis)	Uncommon	Uncommon
Difficulties passing urine (urinary retention)	Uncommon	Not known
Constipation	Uncommon	Rare
Rash	Uncommon	Uncommon
Itching (pruritus)	Uncommon	Rare
Increase of the measured eye pressure	Rare	Not known
Serious allergic reaction which causes swelling of the mouth and face or throat (angioneurotic oedema)	Rare	Rare
Difficulty in sleeping (insomnia)	Rare	Uncommon
Irregular heart beat (atrial fibrillation, supraventricular tachycardia)	Rare	Not known
Feeling your heart beat (palpitations)	Rare	Uncommon
Nosebleed (epistaxis)	Rare	Rare
Inflammation of the tongue (glossitis)	Rare	Not known
Faster heart beat (tachycardia)	Rare	Not known
Tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)	Rare	Uncommon
Difficulties swallowing (dysphagia)	Rare	Not known
Seeing halos around lights or coloured images in association with red eyes (glaucoma)	Rare	Not known
Blurred vision	Rare	Not known
Inflammation of the larynx (laryngitis)	Rare	Not known
Dental caries	Rare	Not known
Inflammation of the gums (gingivitis)	Rare	Rare
Nettle rash (urticaria)	Rare	Rare
Infections or ulcerations of the skin	Rare	Not known
Dryness of the skin	Rare	Not known
Infections of the urinary tract	Rare	Rare
Heart burn (gastrooesophageal reflux disease)	Rare	Not known
Hypersensitivity, including immediate reactions	Not known	Rare
Inflammation of the mouth (stomatitis)	Not known	Rare
Depletion of body water (dehydration)	Not known	Not known
Inflammation in sinuses (sinusitis)	Not known	Not known
Blockage of intestines or absence of bowel movements (intestinal obstruction, including ileus paralytic)	Not known	Not known
Feeling sick (nausea)	Not known	Not known
Severe allergic reaction (anaphylactic reaction)	Not known	Not known
Swelling of joint	Not known	Not known

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 (such as sudden reduction of your blood pressure or dizziness) may occur individually or as part of severe allergic reaction (anaphylactic reaction) after administration of Spiriva Respimat.

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 these occur, please consult your doctor immediately.

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 via HPRa Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Spiriva Respimat

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the inhaler label after 'EXP' or 'Scad'. The expiry date refers to the last day of that month.

Do not freeze.

In-use shelf-life:

Exchange the cartridge latest three months after insertion.

Do not use the Respimat re-usable inhaler for more than one year.

Recommended use: 6 cartridges per inhaler

Note: The functioning of the RESPIMAT re-usable inhaler has been demonstrated in tests for 540 actuations (corresponding to 9 cartridges).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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 inhalation solution and one Respimat inhaler. The cartridge has to be inserted into the inhaler before the first use.

Single pack: 1 Respimat re-usable inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)

Manufacturer

The manufacturer for Spiriva Respimat is: Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, D-55216 Ingelheim am Rhein, Germany or Boehringer Ingelheim Espana, SA, C/ Prats de la Riba, 50, 08174 Sant Cugat del Valles, Barcelona, Spain.

Product is procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number: PPA0465/286/001

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Liechtenstein, Belgium, Luxembourg, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Malta, United Kingdom (Northern Ireland), Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden: Spiriva Respimat
Bulgaria: Спирива Респимат

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Instructions on how to use the Respimat re-usable inhaler

Respimat is an inhaler device that generates a spray for inhalation. Respimat is for you only. One cartridge delivers multiple doses. The Respimat re-usable inhaler allows for the replacement of the cartridge, and can be used with up to 6 cartridges.

Children should use Spiriva Respimat with an adult's assistance.

Read these instructions before you start using Spiriva Respimat.

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



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

How to care for your Respimat re-usable 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 discoloration in the mouthpiece does not affect your Respimat re-usable inhaler performance. If necessary, wipe the outside of your Respimat re-usable inhaler with a damp cloth.

When to replace the inhaler

When you have used an inhaler with 6 cartridges, get a new Spiriva Respimat pack containing an inhaler. Do not use the Respimat re-usable inhaler for more than one year, after having inserted the first cartridge.



Prepare for use

1. Remove clear base

- Keep the cap closed.
- Press the safety catch while pulling off the clear base with your other hand.



2. Insert cartridge

- Insert the cartridge into the inhaler.
- Place the inhaler on a firm surface and push down firmly until it clicks into place.



3. Track cartridge and put the clear base back

- Mark the check-box on inhaler's label to track the number of cartridges.
- Put the clear base back into place until it clicks.



4. Turn

- Keep the cap closed.
- Turn the clear base in the direction of the arrows on the label until it clicks (half a turn).



5. Open

- Open the cap until it snaps fully open.



6. Press

- Point the inhaler toward the ground.
- Press the dose-release button.
- Close the cap.
- Repeat steps 4-6 until a cloud is visible.
- **After a cloud is visible**, repeat steps 4-6 three more times.

Your inhaler is now ready to use and will deliver 60 puffs (30 doses).



Daily use

TURN

- Keep the cap closed.
- **TURN** the clear base in the direction of the arrows on the label until it clicks (half a turn).



OPEN

- **OPEN** the cap until it snaps fully open.



PRESS

- Breathe out slowly and fully.
- Close your lips around the mouthpiece without covering the air vents. Point your inhaler to the back of your throat.
- While taking a slow, deep breath through your mouth, **PRESS** the dose-release button and continue to breathe in slowly for as long as comfortable.
- Hold your breath for 10 seconds or for as long as comfortable.
- Repeat **TURN, OPEN, PRESS** for a total of 2 puffs.
- Close the cap until you use your inhaler again.



When to replace the Spiriva Respimat cartridge

The dose indicator shows how many puffs remain in the cartridge.



60 puffs remaining

Less than 10 puffs remaining. Obtain a new cartridge

Your cartridge is used up. Turn the clear base to loosen it. Your inhaler is now in a locked position. Pull off the cartridge from the inhaler. Insert a new cartridge until it clicks (refer to step 2). The new cartridge will stick out more than the very first cartridge (continue with step 3). Remember to put the clear base back to unlock the inhaler.

Answers to Common Questions

It is difficult to insert the cartridge deep enough.

Did you accidentally turn the clear base before inserting the cartridge? Open the cap, press the dose-release button, then insert the cartridge.

Are you replacing the cartridge? The new cartridge will stick out more than the very first cartridge. Insert it until it clicks, then replace the clear base.

I cannot press the dose-release button.

Did you put the clear base back? If not, put the clear base back to unlock the inhaler. The Respimat re-usable inhaler only functions with the clear base in place.

Did you turn the clear base? If not, turn the clear base in a continuous movement until it clicks (half a turn).

Does the dose indicator on your cartridge display a white arrow on a red background? Your cartridge is used up. Insert a new cartridge and put the clear base back.

It is difficult to remove the cartridge after it is used up.

Pull and turn the cartridge at the same time.

I cannot turn or put the clear base back.

Is the clear base loose and does the dose indicator on your cartridge display a white arrow on a red background? Your cartridge is used up. Insert a new cartridge.

Did you turn the clear base already?

If the clear base has already been turned, follow steps "OPEN" and "PRESS" under "Daily Use" to get your medicine.

My Spiriva Respimat has been used up too early.

Did you use Spiriva Respimat as indicated (two puffs/once daily)? Each cartridge will last 30 days if used at two puffs once daily. **Did you spray in the air often to check whether Spiriva Respimat is working?** Once you have prepared Spiriva Respimat for use, no test-spraying is required if used daily. **Did you take off and put the clear base multiple times back?** Do not remove the clear base before the cartridge is used up. Each time you take off the clear base without cartridge exchange, the dose counter records one puff and the remaining doses are reduced.

My Spiriva Respimat doesn't spray.

Did you insert a cartridge? If not, insert a cartridge. Once your Spiriva Respimat is assembled, do not remove the clear base or the cartridge until the cartridge is used up.

Did you repeat Turn, Open, Press less than three times after inserting the cartridge? Repeat TURN, OPEN, PRESS three times after inserting the cartridge as shown in the steps 4 to 6 under "Prepare for use".

Does the dose indicator on your cartridge display a white arrow on a red background? Your cartridge is used up. Insert a new cartridge.

My Spiriva Respimat sprays automatically.

Was the cap open when you turned the clear base? Close the cap, then turn the clear base.

Did you press the dose-release button when turning the clear base? Close the cap, so the dose-release button is covered, then turn the clear base.

Did you stop when turning the clear base before it clicked? Turn the clear base in a continuous movement until it clicks (half a turn). The dose counter will count each incomplete turn and the number of remaining doses is reduced.

Was the cap open when you replaced the cartridge? Close the cap, then replace the cartridge.