

Package leaflet: Information for the user

Spiolto® Respimat® 2.5 microgram/2.5 microgram, inhalation solution tiotropium/olodaterol

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

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

What Spiolto Respimat is

Spiolto Respimat contains two active substances called tiotropium and olodaterol. These belong to a group of medicines called long-acting bronchodilators. Tiotropium belongs to the subgroup of anticholinergics; olodaterol belongs to the subgroup of long acting beta₂ agonists.

What Spiolto Respimat is used for

Spiolto Respimat helps adult patients 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.

Spiolto Respimat helps to open your airways and make it easier to get air in and out of the lungs. Regular use of Spiolto Respimat can also help you when you have on-going shortness of breath related to your disease, and will help to minimise the effects of the disease on your everyday life. As COPD is a long-term disease you should take Spiolto Respimat every day and not only when you have breathing problems or other symptoms of COPD.

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

Do not take Spiolto Respimat

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Spiolto Respimat

- if you have asthma (you should not take Spiolto Respimat for the treatment of asthma).
- if you have diseases of the heart.

- if you have high blood pressure.
- if you have epilepsy.
- if you have a specific thyroid gland problem called thyrotoxicosis.
- if you have an abnormal widening of an artery called aneurysm.
- if you have diabetes.
- if you have severe hepatic (liver) disease.
- if you have renal (kidney) disease.
- in case of a planned surgery.
- if you have an eye problem called narrow-angle glaucoma.
- if you have prostate problems or have difficulty passing urine.

During treatment with Spiolto Respimat

- **Stop taking the medicine and tell your doctor immediately** if you get tightness of the chest, coughing, wheezing or breathlessness immediately after taking the medicine. These may be signs of a condition called bronchospasm (see section 4).
- 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 (see section 4).
- If you experience any side effects affecting your heart (increase in pulse rate, increase in blood pressure and/or increase in symptoms like chest pain), tell your doctor immediately (see section 4).
- If you experience muscle spasm, muscle weakness or abnormal heart rhythm, consult your doctor as these may be related to low blood levels of potassium (see section 4).

When taking Spiolto 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 taking Spiolto Respimat and immediately consult your doctor for further advice.

Spiolto 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.**

Do not take Spiolto Respimat together with certain medicines containing long-acting β -adrenergic agonists, like salmeterol or formoterol.

If you regularly take certain medicines called short-acting β -adrenergic agents, like salbutamol, continue to take these only to relieve acute symptoms like breathlessness.

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.

Do not take Spiolto Respimat more frequently than once daily.

Children and adolescents

Spiolto Respimat **should not** be given to **children or adolescents (below the age of 18 years)**.

Other medicines and Spiolto Respimat

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines.

In particular, please tell your doctor if you are taking:

- any medicines that may be similar to Spiolto Respimat (contain similar active substances, such as anticholinergic drugs or β -adrenergic agents). You may be more likely to get side effects.

- medicines called beta blockers that are used for high blood pressure or other heart problems (such as propranolol), or for the eye problem called glaucoma (such as timolol). This may result in loss of the effect of Spiolto Respimat
- medicines that lower the amount of potassium in your blood. These include:
 - o steroids (e.g. prednisolone),
 - o diuretics (water tablets),
 - o medicines for breathing problems such as theophylline.
 If you take these medicines together with Spiolto Respimat you may experience symptoms of muscle spasm, muscle weakness or abnormal heart rhythm.
- medicines called tricyclic antidepressants or monoamine oxidase (MAO) inhibitors (like selegiline or moclobemide), that are used to treat neurological or psychiatric disorders like Parkinson's disease or depression; the use of these drugs will increase the likelihood that you get side effects affecting your heart.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 on the ability to drive and use machines have been performed.

If you feel dizzy or if blurred vision occurs while taking Spiolto Respimat, do not drive or use any tools or machines.

Spiolto 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 Spiolto Respimat

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

Spiolto Respimat is for inhalation use only.

Dosage

The recommended dose is:

Spiolto Respimat is effective for 24 hours so you will need to take Spiolto 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 Spiolto 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

There is no relevant use of Spiolto Respimat in the paediatric population (under 18 years).

If you take more Spiolto Respimat than you should

You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, blurred vision, chest pain, high or low blood pressure, faster or irregular heartbeat or feeling of heart beat, dizziness, nervousness, difficulty in sleeping, anxiety, headache, shaking, muscle cramps, nausea, fatigue, malaise, low blood levels of potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm), high blood sugar, or too much acid in your blood (which may cause symptoms of nausea, vomiting, weakness, muscle cramps and more rapid breathing).

If you forget to take Spiolto Respimat

If you forget to inhale a dose, inhale just one dose at the usual time the next day.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Spiolto Respimat

Before you stop taking Spiolto Respimat, you should talk to your doctor or your pharmacist. If you stop taking Spiolto Respimat the signs and symptoms of COPD 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.

If any of the following occurs, **please stop taking this medicine** and consult your doctor immediately.

- Immediate allergic reactions to Spiolto Respimat are rare (they may affect up to 1 in 1,000 people). These reactions may occur individually or as part of a severe allergic reaction (anaphylactic reaction) after administration of Spiolto Respimat. These include rash, nettle rash (urticaria), swelling of the mouth and face, sudden difficulties in breathing (angioneurotic oedema) or other hypersensitivity reactions (such as sudden reduction of your blood pressure or light headedness).
- As with all inhaled medications, tightness of the chest, associated with coughing, wheezing or breathlessness may occur immediately after inhalation (paradoxical bronchospasm). The frequency cannot be estimated from the available data.
- seeing halos around lights or coloured images in association with red eyes (glaucoma). The frequency cannot be estimated from the available data.
- blockage of intestines or absence of bowel movements (intestinal obstruction, including ileus paralytic). The frequency cannot be estimated from the available data.

Other possible side effects:

Uncommon (may affect up to 1 in 100 people)

- faster heart beat (tachycardia)
- dizziness
- headache
- cough
- hoarseness (dysphonia)
- dry mouth

Rare (may affect up to 1 in 1,000 people)

- irregular heart beat (atrial fibrillation)
- rapid heartbeat (supraventricular tachycardia)
- feeling your heartbeat (palpitations)
- high blood pressure (hypertension)

- difficulties passing urine (urinary retention)
- infections of the urinary tract
- painful urination (dysuria)
- sore throat (pharyngitis)
- inflammation of the larynx (laryngitis)
- inflammation of the gums (gingivitis)
- inflammation of the mouth (stomatitis)
- fungal infections of the mouth and throat (oropharyngeal candidiasis)
- nosebleed (epistaxis)
- difficulty in sleeping (insomnia)
- blurred vision
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- constipation
- feeling sick (nausea)
- itching (pruritus)
- joint pain (arthralgia)
- swelling of joint
- back pain

Not known (frequency cannot be estimated from the available data)

- increase of the measured eye pressure
- nasopharyngitis
- inflammation in sinuses (sinusitis)
- difficulties swallowing (dysphagia)
- inflammation of the tongue (glossitis)
- heart burn (gastrooesophageal reflux disease)
- dental caries
- infections or ulcerations of the skin
- dryness of the skin
- depletion of body water (dehydration)

You may also experience side effects which are known to occur with certain medicines for breathing problems similar to Spiolto Respimat (beta-adrenergic agents). These may be irregular heartbeat, chest pain, low blood pressure, shaking, nervousness, muscle cramps, fatigue, malaise, low blood levels of potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm), high blood sugar, or too much acid in your blood (which may cause symptoms of nausea, vomiting, weakness, muscle cramps and more rapid breathing).

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 below). By reporting side effects, you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store Spiolto 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 cartridge label after EXP. The expiry date refers to the last day of the 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 Spiolto Respimat contains

The active substances are tiotropium and olodaterol. The delivered dose is 2.5 microgram tiotropium (as bromide monohydrate) and 2.5 microgram olodaterol (as hydrochloride) per puff.

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 for pH adjustment

What Spiolto Respimat looks like and contents of the pack

Spiolto Respimat 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)

Triple pack: 1 Respimat re-usable inhaler and 3 cartridges, providing 60 puffs (30 medicinal doses) each

Single refill pack: 1 cartridge, providing 60 puffs (30 medicinal doses)

Triple refill pack: 3 cartridges, providing 60 puffs (30 medicinal doses) each

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder for Spiolto Respimat is:

Boehringer Ingelheim International GmbH
Binger Straße 173
55216 Ingelheim am Rhein
Germany

The manufacturer for Spiolto Respimat is:

Boehringer Ingelheim Pharma GmbH & Co. KG
Binger Straße 173
55216 Ingelheim am Rhein
Germany

Boehringer Ingelheim España, SA
c/ Prat de la Riba, 50
08174 Sant Cugat del Vallès (Barcelona)
Spain

Boehringer Ingelheim France
100-104 Avenue de France
75013 Paris
France

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

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

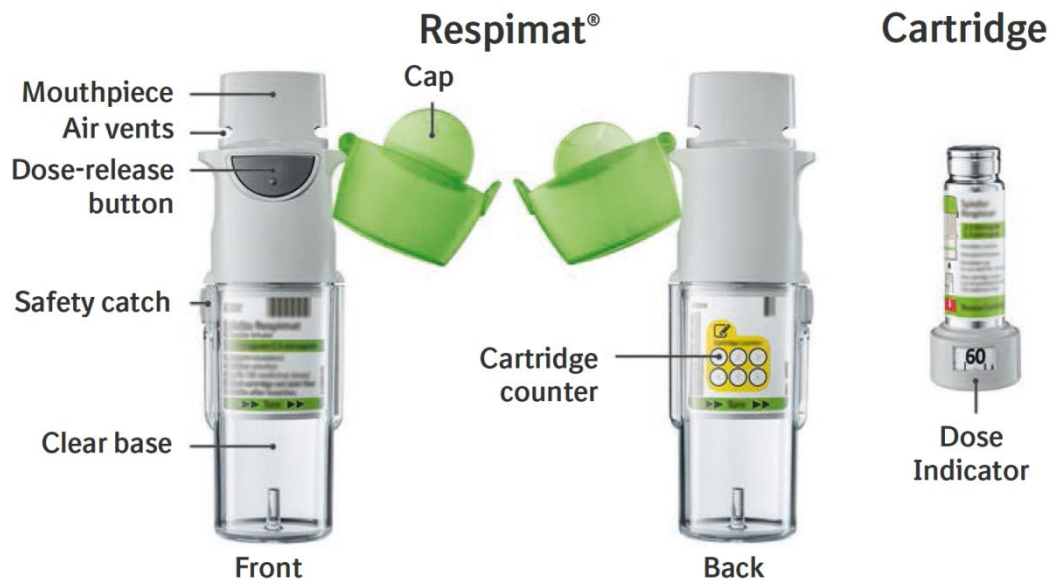
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Instructions on how to use the Respimat re-usable inhaler

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.

Read these instructions before you start using Spiolto Respimat.

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



- If Spiolto Respimat has not been used for more than 7 days release one puff towards the ground.
- If Spiolto 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 Spiolto 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.



<p>4. Turn</p> <ul style="list-style-type: none"> • Keep the cap closed. • Turn the clear base in the direction of the arrows on the label until it clicks (half a turn). 	
<p>5. Open</p> <ul style="list-style-type: none"> • Open the cap until it snaps fully open. 	
<p>6. Press</p> <ul style="list-style-type: none"> • 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. <p>Your inhaler is now ready to use and will deliver 60 puffs (30 doses).</p>	

Daily use

<p>TURN</p> <ul style="list-style-type: none"> • Keep the cap closed. • TURN the clear base in the direction of the arrows on the label until it clicks (half a turn). 	 <p>Arrows</p>
<p>OPEN</p> <ul style="list-style-type: none"> • OPEN the cap until it snaps fully open. 	 <p>Cap</p>
<p>PRESS</p> <ul style="list-style-type: none"> • 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. 	 <p>Air vent</p> <p>TWO PUFFS ONCE DAILY</p>

When to replace the Spiolto 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 Spiolto Respimat has been used up too early.

Did you use Spiolto 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 Spiolto Respimat is working? Once you have prepared Spiolto 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 Spiolto Respimat doesn't spray.

Did you insert a cartridge? If not, insert a cartridge. Once your Spiolto 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 Spiolto 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.