

# Spiolto<sup>®</sup> Respimat<sup>®</sup>

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Spiolto Respimat?

Spiolto Respimat contains the active ingredients tiotropium (as bromide monohydrate) and olodaterol (as hydrochloride). Spiolto Respimat is used for the treatment of Chronic Obstructive Pulmonary Disease (COPD). COPD is a serious lung condition that can cause difficulty in breathing and constant coughing.

For more information, see Section [1. Why am I using Spiolto Respimat?](#) in the full CMI.

### 2. What should I know before I use Spiolto Respimat?

Do not use if you have ever had an allergic reaction to tiotropium, olodaterol, atropine, medicines like atropine (e.g. ipratropium or oxitropium) or any of the ingredients listed at the end of this leaflet.

**Talk to your doctor if you have any other medical conditions, take any other medicines, vitamins or supplements or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Spiolto Respimat?](#) in the full CMI.

### **3. What if I am taking or using other medicines?**

Some medicines may interfere with Spiolto Respimat and affect how it works.

A list of these medicines is in Section [3. What if I am taking or using other medicines?](#) in the full CMI.

### **4. How do I use Spiolto Respimat?**

- Spiolto Respimat is for inhalation use only.
- Read the Instructions for Use and follow the diagrams that show you how to use the Spiolto Respimat reusable inhaler.
- Take TWO PUFFS, once a day at the same time of the day. You need to take two puffs to get the full dose.

More instructions can be found in Section [4. How do I use Spiolto Respimat?](#) in the full CMI.

## 5. What should I know while using Spiolto Respimat?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Stop using Spiolto Respimat and tell your doctor immediately if you get sudden tightness of the chest, coughing, wheezing or breathlessness immediately after using Spiolto Respimat.</li><li>● Remind any doctor, dentist or pharmacist you visit that you are using Spiolto Respimat.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not use Spiolto Respimat to relieve an acute attack of breathlessness or wheezing.</li><li>● Do not stop using your medicine or lower the dosage without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>● Spiolto Respimat may cause dizziness or blurred vision in some people.</li></ul>

	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how Spiolto Respimat affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep Spiolto Respimat in a cool dry place where the temperature stays below 30°C. Do not freeze.</li> <li>• Replace the cartridge not later than three months after insertion.</li> <li>• The recommended use is 6 cartridges per Respimat re-usable inhaler.</li> </ul>

For more information, see Section [5. What should I know while using Spiolto Respimat?](#) in the full CMI.

## 6. Are there any side effects?

Side effects that require urgent medical attention include allergic reaction, chest pain (angina pectoris/heart attack), severe pain in the stomach with bloating, gut cramps and vomiting and signs of metabolic acidosis (increased rate of breathing, faster heartbeat, headache, confusion, weakness, tiredness, nausea, vomiting and loss of appetite).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Spiolto<sup>®</sup> Respimat<sup>®</sup>

**Active ingredients:** *tiotropium (as bromide monohydrate) / olodaterol (as hydrochloride)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Spiolto Respimat. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Spiolto Respimat.**

**Where to find information in this leaflet:**

- [1. Why am I using Spiolto Respimat?](#)
- [2. What should I know before I use Spiolto Respimat?](#)
- [3. What if I am taking or using other medicines?](#)
- [4. How do I use Spiolto Respimat?](#)
- [5. What should I know while using Spiolto Respimat?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Spiolto Respimat?

**Spiolto Respimat contains the active ingredients tiotropium (as bromide monohydrate) and olodaterol (as hydrochloride).** Tiotropium belongs to a group of medicines called anticholinergics. Olodaterol belongs to a group of medicines called long-acting bronchodilators. These medicines are used to relax the breathing tubes

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or air passages that carry air to and from the lungs and to keep the air passages in the lungs open and make breathing easier.

Spiolto Respimat is used for the treatment of Chronic Obstructive Pulmonary Disease (COPD). COPD is a serious lung condition that can cause difficulty in breathing and constant coughing.

The term COPD is associated with the conditions chronic bronchitis and emphysema. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up phlegm.

Regular use of Spiolto Respimat can also help when you have ongoing shortness of breath related to your disease, and will help minimise the effects of the disease on your everyday life.

As COPD is a long-term condition, you should take Spiolto Respimat every day, even if you do not have breathing problems or other symptoms of COPD.

## 2. What should I know before I use Spiolto Respimat?

### Warnings

**Do not use Spiolto Respimat to relieve an acute attack of breathlessness or wheezing.** You will need a different type of medicine known as a 'reliever' for this. Spiolto Respimat should only be used for maintenance treatment of your COPD.

**Do not use Spiolto Respimat if you are allergic to:**

- tiotropium (as bromide monohydrate) or olodaterol (as hydrochloride), or any of the ingredients listed at the end of this leaflet.
- atropine or substances related to it, e.g. ipratropium or oxitropium.

**Do not use Spiolto Respimat to treat asthma.** Safety and effectiveness in the treatment of asthma has not been established.

**Tell your doctor if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

**Check with your doctor if:**

- You have or have had any of the following medical conditions:
  - asthma (you should not use Spiolto Respimat to treat your asthma)
  - acute worsening of your breathing problems
  - heart problems
  - high blood pressure
  - seizures
  - overactive thyroid gland (thyrotoxicosis)
  - high pressure in the eye (glaucoma)
  - kidney or liver problems
  - problems with passing urine
  - problems with your prostate gland
  - diabetes



- severe liver problems

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Tell your doctor if you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

## **Children and adolescents**

**Do not give this medicine to a child or adolescent under the age of 18 years.**

Safety and effectiveness in children younger than 18 years have not been established.

## **Eyes**

**Do not allow the mist to enter your eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes, stop using Spiolto Respimat and immediately consult your doctor for further advice.**

If the mist enters the eye, it 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.

## Device

The Spiolto Respimat re-usable inhaler can only be used with Spiolto Respimat cartridges.

### 3. What if I am taking or using other medicines?

Tell your doctor or pharmacist if you are taking any other medicines/inhalers, including any medicines/inhalers, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines and Spiolto Respimat may interfere with each other. These include:**

- Similar medicines used to treat your breathing problems, including other anticholinergic medicines such as ipratropium
- Medicines that can lower the amount of potassium in your blood. These include medicines used to treat breathing problems such as theophylline, steroids such as prednisolone and diuretics (water tablets)
- Medicines used to treat high blood pressure, heart conditions, glaucoma and migraine such as propranolol (beta-blockers)
- Medicines used for glaucoma, including eye drops such as timolol

- Medicines used to treat depression and other mental disorders such as tricyclic antidepressants (amitriptyline, nortriptyline, clomipramine, dothiepin, doxepin and imipramine) or Monoamine oxidase (MAO) inhibitors (like selegiline, moclobemide, phenelzine and tranylcypromine).

You may need to take different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Spiolto Respimat.**

## **4. How do I use Spiolto Respimat?**

### **How much to use**

**Inhale TWO PUFFS, once a day at the same time of the day.** You need to take two puffs to get the full dose. Two puffs are equal to one dose.

Each dose of Spiolto Respimat will keep your air passages open for 24 hours.

Follow the instructions provided and use Spiolto Respimat until your doctor tells you to stop.

### **When to use Spiolto Respimat**

Spiolto Respimat should be used at about the same time each day.

## How to use Spiolto Respimat

- **Spiolto Respimat is for inhalation use only.** The solution for inhalation is contained in the Spiolto Respimat cartridge and inhaled using the Spiolto Respimat re-usable inhaler supplied with the medicine.
- Make sure that you know how to use your Spiolto Respimat re-usable inhaler properly.
- **Read the Instructions for Use and follow the diagrams that show you how to use the Spiolto Respimat re-usable inhaler.**
- **The Instructions for Use are also available via the following hyperlink:** <https://medsinfo.com.au/media/byispiri>

Use the Spiolto Respimat re-usable inhaler supplied in the pack to breathe in the solution containing the medicine from the Spiolto Respimat cartridge.

Insert the Spiolto Respimat cartridge into the Spiolto Respimat re-usable inhaler to prepare the inhaler for use.

The Spiolto Respimat re-usable inhaler releases a mist of solution slowly and gently, making it easy to inhale it into your lungs where it is needed. The mist containing the medication is released by pressing the dose release button.

If you do not understand the instructions on how to use the Spiolto Respimat re-usable inhaler, ask your doctor or pharmacist for help.

## **If you forget to use Spiolto Respimat**

**If you forget to use your Spiolto Respimat, use it as soon as you remember.**

**If it is almost time for your next dose, skip the dose you missed and inhale just one dose at your usual time the next day.**

**Do not take a double dose to make up for the dose that you missed.** This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

## **If you use too much Spiolto Respimat**

If you think that you have used too much Spiolto Respimat, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include:

- chest pain

- high or low blood pressure, dizziness, light-headedness
- blurred vision
- changes in the heart rate (fast, slow or irregular), palpitations
- nervousness or feeling anxious
- inability to sleep
- headache
- shaking or tremors
- dry mouth
- muscle cramps or spasm
- muscle weakness
- feeling sick, also called nausea
- stomach pain
- constipation
- fatigue
- generally feeling unwell
- passing large amounts of urine, excessive thirst and having a dry mouth and skin
- difficulty passing urine
- increased rate of breathing.

## **5. What should I know while using Spiolto Respimat?**

### **Things you should do**

- **Stop using Spiolto Respimat and tell your doctor immediately if you get sudden tightness of the**

**chest, coughing, wheezing or breathlessness immediately after using the Spiolto Respimat.**

These may be signs of a condition called bronchospasm.

- **Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- Remind any doctor, dentist or pharmacist you visit that you are using Spiolto Respimat, especially if you are about to start any new medicine or if you are going to have surgery.
- **If you are a smoker, you should stop smoking.** Your doctor or pharmacist can advise you on the steps to take to quit smoking.

### **Tell your doctor immediately if:**

- You become pregnant while using Spiolto Respimat.

### **Things you should not do**

- **Do not use Spiolto Respimat to relieve an acute attack of breathlessness or wheezing. If you become wheezy or tight in the chest before your next dose of Spiolto Respimat is due, use a 'reliever puffer' in the usual way.** Spiolto Respimat should only be used for maintenance treatment of your COPD.
- Do not use Spiolto Respimat to treat any other complaints unless your doctor tells you to.

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take any other medicines for your breathing problems without checking with your doctor.
- Do not stop using your medicine or lower the dosage without checking with your doctor. If you stop using it suddenly or lower the dosage, the signs and symptoms of your COPD may worsen.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Spiolto Respimat affects you.**

Spiolto Respimat may cause dizziness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

## **Looking after your medicine**

- Refer to the Respimat re-usable inhaler Instructions for Use on how to clean and take care of your Spiolto Respimat.
- Clean the mouthpiece including the metal part inside the mouthpiece with a damp cloth or tissue only, at least once a week.
- It is important to keep your inhaler clean and dry. It may not work as well if it gets dirty.
- **Exchange cartridge not later than three months after insertion.**



- **Do not use the Respimat re-usable inhaler for more than one year, after having inserted the first cartridge.**
- The recommended use is 6 cartridges per Respimat re-usable inhaler.
- Keep Spiolto Respimat in a cool dry place where the temperature stays below 30°C. Do not freeze.

Store it away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date located on the cartridge.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Do not be alarmed by the following list of side effects.** You may not experience any of them.

**Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Brain and nerves:</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• dizziness</li> <li>• tiredness (fatigue)</li> <li>• shaking</li> <li>• nervousness</li> <li>• generally feeling unwell</li> <li>• trouble sleeping.</li> </ul> <p><b>Nose and sinus:</b></p> <ul style="list-style-type: none"> <li>• runny nose or nose bleeds</li> <li>• sinusitis, a feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell.</li> </ul> <p><b>Mouth, throat and airways:</b></p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dry or sore mouth or throat and discomfort when swallowing; swollen, red, sore tongue</li> <li>● Inflammation of the gums (gingivitis) or tooth decay</li> <li>● sore, creamy-yellow, raised patches in the mouth or throat (oral thrush)</li> <li>● hoarse voice</li> <li>● flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills</li> <li>● shortness of breath, cough, or chest infections.</li> </ul> <p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>● a burning sensation in the chest rising up to the throat, also known as heartburn</li> <li>● feeling sick (nausea)</li> <li>● a change in bowel movements, e.g. constipation.</li> </ul>	

Less serious side effects	What to do
<p><b>Metabolism and Nutrition:</b></p> <ul style="list-style-type: none"> <li>• dehydration.</li> </ul> <p><b>Musculoskeletal and Connective tissue:</b></p> <ul style="list-style-type: none"> <li>• back or joint pain, joint swelling</li> <li>• muscle spasm.</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>• rash or dry skin</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Eyes:</b></p> <ul style="list-style-type: none"> <li>• blurred vision</li> <li>• seeing halos around lights or coloured images in association with red eyes; high pressure in the eye (glaucoma).</li> </ul> <p><b>Mouth, throat and airways:</b></p> <ul style="list-style-type: none"> <li>• worsening of breathing problems (induced by</li> </ul>	<p><b>Speak with your doctor as soon as possible if you have any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>the inhalation process).  Inhaled medicines such as Spiolto Respimat may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation</p> <ul style="list-style-type: none"> <li>● increased rate of breathing</li> <li>● difficulty swallowing.</li> </ul> <p><b>Heart:</b></p> <ul style="list-style-type: none"> <li>● changes in the rhythm or rate of heartbeat (fast, slow or irregular)</li> <li>● feeling of fluttering, racing or skipping heart beats (palpitations)</li> <li>● increase or decrease in blood pressure.</li> </ul> <p><b>Bladder:</b></p> <ul style="list-style-type: none"> <li>● difficulty passing urine</li> <li>● signs of a urinary tract infection such as: <ul style="list-style-type: none"> <li>○ a frequent need to urinate</li> </ul> </li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>○ only passing a few drops of urine</li> <li>○ burning pain or a 'scalding' sensation when urinating</li> <li>○ feeling that the bladder is still full after urinating</li> <li>○ pain above the pubic bone</li> <li>○ blood in your urine.</li> </ul> <p><b>Signs of low potassium levels in the blood:</b></p> <ul style="list-style-type: none"> <li>● muscle spasm</li> <li>● muscle weakness</li> <li>● abnormal heart rhythm.</li> </ul> <p><b>Signs of high blood sugar levels:</b></p> <ul style="list-style-type: none"> <li>● passing large amounts of urine</li> <li>● excessive thirst</li> <li>● dry mouth and skin.</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>● skin infection or skin ulcer.</li> </ul>	

# Very serious side effects

Very serious side effects	What to do
<p><b>Signs of an allergic reaction:</b></p> <ul style="list-style-type: none"> <li>● shortness of breath, wheezing or difficulty breathing</li> <li>● swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing</li> <li>● swelling of other parts of the body</li> <li>● rash, itching or hives on the skin.</li> </ul> <p><b>Heart:</b></p> <ul style="list-style-type: none"> <li>● chest pain (angina pectoris/heart attack).</li> </ul> <p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>● severe pain in the stomach with bloating, gut cramps and vomiting.</li> </ul> <p><b>Signs of metabolic acidosis:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

<b>Very serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● increased rate of breathing</li> <li>● faster heartbeat</li> <li>● headache or confusion</li> <li>● weakness</li> <li>● tiredness</li> <li>● nausea and vomiting</li> <li>● loss of appetite.</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**



## 7. Product details

This medicine is only available with a prescription.

### What Spiolto Respimat contains

<b>Active ingredients (main ingredients)</b>	Per puff: <ul style="list-style-type: none"><li>• 2.5 micrograms tiotropium (as bromide monohydrate), and</li><li>• 2.5 micrograms olodaterol (as hydrochloride).</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• benzalkonium chloride</li><li>• disodium edetate</li><li>• hydrochloric acid</li><li>• purified water.</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Spiolto Respimat looks like

Spiolto Respimat is available as a solution for inhalation contained in the cartridge. The Spiolto Respimat reusable inhaler (with a light-green coloured cap) enables you to inhale the medicine from the cartridge. (AUST R 326008).

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

**Double pack:** 1 Spiolto Respimat re-usable inhaler and 2 Spiolto Respimat cartridges, providing 60 puffs (30 doses) each.

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

**Single refill pack:** 1 Spiolto Respimat cartridge, providing 60 puffs (30 doses).

**Triple refill pack:** 3 Spiolto Respimat cartridges, providing 60 puffs (30 doses) each.

Not all pack sizes may be marketed.

## **Who distributes Spiolto Respimat**

Spiolto Respimat is distributed in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

<http://www.boehringer-ingelheim.com.au/>

This leaflet was revised in May 2024.

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