

# Spiriva<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.

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

Spiriva Respimat contains the active ingredient tiotropium. Spiriva Respimat is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD) and asthma. If used to treat asthma you **MUST** use Spiriva Respimat in addition to other medicines called inhaled corticosteroids.

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

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

Do not use if you have ever had an allergic reaction to tiotropium, 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 Spiriva Respimat?](#) In the full CMI.

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

Some medicines may interfere with Spiriva 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 Spiriva Respimat?**

- Spiriva Respimat is for inhalation use only.
- **Read the Instructions for Use and follow the diagrams that show you how to use the Spiriva Respimat re-usable inhaler.**
- The recommended dose is 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 Spiriva Respimat?](#) In the full CMI.

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Spiriva Respimat.</li><li>• Tell your doctor immediately if your breathing becomes more difficult while you are taking Spiriva Respimat.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use Spiriva Respimat to relieve an acute attack of breathlessness or wheezing.</li><li>• Do not take Spiriva Respimat more frequently than once daily.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Spiriva Respimat may cause dizziness or blurred vision in some people.</li><li>• Be careful before you drive or use any machines or tools until</li></ul>

	you know how Spiriva Respimat affects you.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep Spiriva Respimat in a cool dry place where the temperature stays below 25°C. Do not freeze.</li> <li>• Exchange cartridge not later than three months after insertion.</li> </ul>

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

## 6. Are there any side effects?

A common side effect in patients with COPD is dry mouth, which is usually mild.

**Serious potential side effects that require medical attention include:** worsening of breathing, difficulty swallowing, palpitations, vision changes, pain or difficulty passing urine, urinary tract infection and skin infection or ulcer. **Patients who experience an allergic reaction or severe pain in the stomach with bloating, gut cramps and vomiting require urgent medical attention.**

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.



# Spiriva<sup>®</sup> Respimat<sup>®</sup>

Active ingredient: *tiotropium*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Spiriva 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 Spiriva Respimat.**

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

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

## 1. Why am I using Spiriva Respimat?

**Spiriva Respimat contains the active ingredient tiotropium (as bromide monohydrate).** It belongs to a group of medicines called anticholinergics. Spiriva Respimat improves breathing by relaxing the breathing tubes or air passages that carry air to and from the lungs.

Spiriva Respimat is used to make breathing easier for people with:

- chronic obstructive pulmonary disease (COPD)
- asthma.

## **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. Spiriva Respimat helps to improve your COPD condition and prevent exacerbations (periodic worsening of symptoms) from occurring.

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

## **Asthma**

Asthma is a serious lung condition where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke, air pollution or other things that irritate your lungs.

The common symptoms of asthma include breathlessness, wheezing, a cough (sometimes brought on by exercise), and a feeling of tightness in the chest.

When used to treat asthma, you MUST use Spiriva Respimat every day in addition to other medicines called inhaled corticosteroids.

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

### Warnings

**Do not use Spiriva Respimat to treat an acute asthma attack or sudden attack of breathlessness, wheezing or coughing.** You will need a different type of medicine known as a 'reliever' for this.

**Tell your doctor immediately if you get sudden tightness of the chest, coughing, wheezing or breathlessness immediately after using Spiriva Respimat.**

These may be signs of a condition called bronchospasm. Patients with asthma have an increased risk of developing this condition.

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

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

**Check with your doctor if:**

- You have or have had any of the following medical conditions:

- High pressure in the eye (glaucoma)
- Kidney or liver problems
- Problems with your prostate gland
- Problems passing urine
- You have suffered from a heart attack during the last 6 months or from any unstable or life threatening irregular heart beat or severe heart failure within the past year.

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 breast-feeding or intend to breastfeed.

Spiriva Respimat is not generally recommended for use in pregnant women.

Spiriva Respimat should not be used whilst breastfeeding unless the expected benefit outweighs any possible risk to the infant.

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

## **Children and adolescents**

**Do not give Spiriva Respimat to children below the age of 6 years.** Spiriva Respimat is only for the treatment of asthma in children aged 6 years and older.

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

## Eyes

**Do not allow the mist to enter your eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes 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 Spiriva Respimat Re-usable inhaler can only be used with Spiriva Respimat cartridges.

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

Tell your doctor or pharmacist if you are taking any other medicines or 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 Spiriva Respimat may interfere with each other. These include:**

- Other anticholinergic medicines such as glycopyrronium, aclidinium, umeclidinium or ipratropium.

You may need 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 Spiriva Respimat.**

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

**If you have been prescribed Spiriva Respimat for your asthma it must be added on to your treatments that include an inhaled corticosteroid.**

### **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.

**Do not take more than the recommended dose.**

Follow all the directions given to you by your doctor or pharmacist carefully.

### **When to use Spiriva Respimat**

Use Spiriva Respimat at about the same time each day.

### **How to use Spiriva Respimat**

- **Spiriva Respimat is for inhalation use only.**

- Make sure that you know how to use your Spiriva Respimat reusable inhaler properly.
- **Read the Instructions for Use and follow the diagrams that show you how to use the Spiriva Respimat re-usable inhaler.**
- **The Instructions for Use are also available via the following hyperlink: <https://medsinfo.com.au/media/byisprri>**
- Use the Spiriva Respimat re-usable inhaler supplied in the pack to breathe in the solution containing the medicine from the Spiriva Respimat cartridge.
- Insert the Spiriva Respimat cartridge into the Spiriva Respimat re-usable inhaler to prepare the inhaler for first use.
- The Spiriva 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 Spiriva Respimat re-usable inhaler, ask your doctor or pharmacist for help.
- Continue to use Spiriva Respimat for as long as your doctor tells you.

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

**If you forget to use your Spiriva 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 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 Spiriva Respimat**

If you think that you have used too much Spiriva 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 fast or irregular heartbeat, blurred vision, nausea, stomach pain, dry mouth, constipation, difficulty passing urine.

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

### Things you should do

#### Tell your doctor immediately if:

- You become pregnant while using Spiriva Respimat.
- Your breathing becomes more difficult while you are using Spiriva Respimat.

**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 Spiriva Respimat, especially if you are about to start any new medicine or if you are going to have surgery.

#### **Pay attention to oral hygiene.**

Dry mouth which has been observed in medicines like Spiriva Respimat may in the long term be associated with tooth decay.

**If you are a smoker, you should stop smoking.** Your doctor or pharmacist can advise you on the steps to take to quit smoking.

**If you have a COPD or Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.**

**If you have been prescribed Spiriva Respimat for your asthma it must be added on to your treatments that include an inhaled corticosteroid. Continue taking the inhaled corticosteroid as prescribed by your doctor, even if you feel better.**

## **Things you should not do**

- **Do not use Spiriva Respimat to relieve an acute attack of breathlessness or wheezing. If you become wheezy or tight in the chest before your next dose of Spiriva Respimat is due, use a 'reliever puffer' in the usual way.**
- Do not use Spiriva 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.
- Spiriva Respimat should only be used as the maintenance treatment of your COPD or asthma.
- **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 condition may worsen.
- **Do not take Spiriva Respimat more frequently than once daily.**

## Driving or using machines

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

This medicine 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 Spiriva Respimat re-usable inhaler Instructions for Use on how to clean and take care of your Spiriva 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 the cartridge not later than three months after insertion.**
- **Do not use the Respimat re-usable inhaler for more than one year.**
- **The recommended use is 6 cartridges per Spiriva Respimat re-usable inhaler.**
- **Keep Spiriva Respimat in a cool dry place where the temperature stays below 25°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 lists 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>• dizziness</li> <li>• trouble sleeping.</li> </ul> <p><b>Nose and sinus:</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>● nose bleeds</li> </ul> <p><b>Mouth, throat and airways:</b></p> <ul style="list-style-type: none"> <li>● dry mouth (usually mild)</li> <li>● sore mouth, gums, or throat; swollen, red, sore tongue</li> <li>● sore, creamy-yellow, raised patches in the mouth or throat (oral thrush)</li> <li>● hoarse voice</li> <li>● cough</li> </ul> <p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>● heartburn</li> <li>● constipation.</li> </ul> <p><b>Metabolism and Nutrition:</b></p> <ul style="list-style-type: none"> <li>● dehydration</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>● dry skin</li> <li>● rash.</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>• difficulty swallowing</li><li>• worsening of breathing problems (induced by the inhalation process). Inhaled medicines such as Spiriva Respimat may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation.</li></ul> <p><b>Heart:</b></p>	<p><b>Speak to 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>
<ul style="list-style-type: none"> <li>● feeling of fluttering, racing or skipping heart beats (palpitations).</li> </ul> <p><b>Bladder:</b></p> <ul style="list-style-type: none"> <li>● difficulty or pain when passing urine.</li> <li>● signs of a urinary tract infection: <ul style="list-style-type: none"> <li>○ a frequent need to urinate</li> <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> </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 data-bbox="204 432 647 533"><b>Signs of an allergic reaction:</b></p> <ul data-bbox="204 568 778 1279" style="list-style-type: none"><li data-bbox="204 568 699 734">● shortness of breath, wheezing or difficulty breathing</li><li data-bbox="204 752 778 1032">● swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing</li><li data-bbox="204 1050 778 1151">● swelling of other parts of the body</li><li data-bbox="204 1169 762 1279">● rash, itching or hives on the skin.</li></ul> <p data-bbox="204 1305 632 1357"><b>Gut and digestion:</b></p> <ul data-bbox="204 1391 727 1608" style="list-style-type: none"><li data-bbox="204 1391 727 1608">● severe pain in the stomach with bloating, gut cramps and vomiting.</li></ul>	<p data-bbox="810 432 1378 819"><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>

**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 Spiriva Respimat contains

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

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

## What Spiriva Respimat looks like

Spiriva Respimat is composed of one cartridge with solution for inhalation and one Respimat re-usable inhaler. (AUST R 325662).

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

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

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

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

\*Not all pack sizes may be marketed.

## Who distributes Spiriva Respimat

Spiriva Respimat is distributed in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

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

This Consumer Medicine Information was prepared in February 2024.

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