

# Spiriva®

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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?

Spiriva capsules contain the active ingredient tiotropium. Spiriva is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD).

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

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

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 the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, 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?](#) in the full CMI.

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

Some medicines may interfere with Spiriva and affect how it works.

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

### 4. How do I use Spiriva?

- The recommended dose for adults is 1 capsule to be inhaled, once a day.
- Use the HandiHaler device to inhale the powder in the capsules
- Do not swallow the capsules.

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

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

Things you should do	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Spiriva.</li><li>• Tell your doctor immediately if your</li></ul>

	breathing becomes more difficult while you are taking Spiriva.
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not use Spiriva more frequently than once daily.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how Spiriva affects you.</li> <li>• Spiriva may cause dizziness or blurred vision in some people.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your capsules in a cool, dry place where the temperature stays below 25°C. Do not store your capsules in the freezer.</li> <li>• Keep your capsules in the pack until it is time to take them.</li> </ul>

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

## 6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

A common side effect is dry mouth, which is usually mild.

Side effects that require urgent medical attention include allergic reaction, changes in heart rate or palpitations and severe pain in the stomach with bloating, gut cramps and vomiting.

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>

**Active ingredient:** *tiotropium*

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## Consumer Medicine Information (CMI)

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

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

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

## 1. Why am I using Spiriva?

**Spiriva capsules contain the active ingredient tiotropium.** It belongs to a group of medicines called anticholinergics.

**Spiriva is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD).**

This helps to improve your condition and to prevent exacerbations (periodic worsening of symptoms) from occurring.

Spiriva improves breathing by relaxing the air passages that carry air to and from the lungs. It begins to act within 30 minutes after use and the effect should last a full day.

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

### **Warnings**

**Do not use Spiriva to treat a sudden attack of breathlessness, wheezing or coughing.** You will need a different type of medicine.

### **Do not use Spiriva if:**

- You are allergic to tiotropium, or any of the ingredients listed at the end of this leaflet.
- You are allergic to atropine or substances related to it, e.g. ipratropium or oxitropium.
- You have been told by your doctor that you have an intolerance to some sugars, or an allergy to milk proteins (which may be contained in small amounts in the ingredient lactose monohydrate).

## **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 with 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 breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved. Spiriva is not generally recommended for use in pregnant women.

## **Children and adolescents**

Do not give this medicine to children or adolescents (below the age of 18 years).

## Eyes

**Do not allow the powder to enter into the 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 powder 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).

## Device

Use this medicine only with the HandiHaler® device.

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

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

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

- Other anticholinergic medicines used to treat COPD, 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.**

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

### **How much to use**

The recommended dose for adults is 1 capsule to be inhaled, once a day.

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

### **When to use Spiriva**

Spiriva should be used at about the same time each day.

### **How to use Spiriva**

- **Inhale the powder in the capsules only using the HandiHaler device.**
- **Do not swallow the capsules.**
- **Do not open the capsules.** If you open the capsules, the small amount of powder inside may be lost, or you may accidentally get the powder in your eyes.
- **Use each strip of 5 capsules within 5 days of first opening the strip.**
- **Read the HandiHaler Instructions for Use that are supplied with the product. These instructions are also available via the following hyperlink:**  
[www.medsinfo.com.au/media/byispihh](http://www.medsinfo.com.au/media/byispihh)

- **Pierce the capsule only once using the HandiHaler device.** If you pierce it more than once, the capsule may break and pieces of gelatin from the capsule shell, small enough to pass the sieve, may be inhaled into your mouth or throat. Gelatin is not harmful and small particles swallowed or inhaled will be digested or absorbed and are not expected to cause undesirable effects.
- **Do not allow the powder to enter into the eyes.** Should this occur, immediately flush your eyes with cold tap water for several minutes.
- If you have any problems inhaling Spiriva using the HandiHaler device, ask your doctor or pharmacist for advice.

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

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**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 Spiriva**

If you think that you have used too much Spiriva, 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 heart beat, blurred vision, nausea, stomach pain, dry mouth, constipation and difficulty passing urine.

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

### **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are using Spiriva, especially if you are about to start any new medicine or if you are going to have surgery.
- 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.

- It is very important to follow the HandiHaler Instructions for Use carefully.
- If you are a smoker, 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 Spiriva.
- Your breathing becomes more difficult while you are using Spiriva.

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

- Do not use Spiriva to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use Spiriva 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 affects you.**

Spiriva 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 HandiHaler Instructions for Use on how to clean and take care of your HandiHaler.

- Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep well.
- Keep your capsules in a place where the temperature stays below 25°C. Do not store your capsules in the freezer.
- Store it in a cool dry place 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.

## **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

Less serious side effects	What to do
<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> <ul style="list-style-type: none"><li>• 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> <ul style="list-style-type: none"><li>• dry mouth: this is usually mild</li><li>• sore mouth, gums, or throat</li><li>• swollen, red, sore tongue</li><li>• oral thrush</li><li>• hoarse voice</li><li>• cough.</li></ul>	<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>
<b>Gut and digestion:</b> <ul style="list-style-type: none"> <li>• constipation.</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<b>Eyes:</b> <ul style="list-style-type: none"> <li>• blurred vision</li> <li>• seeing halos around lights or coloured images in association with red eyes</li> <li>• high pressure in the eye (glaucoma).</li> </ul> <b>Mouth, throat and airways:</b> <ul style="list-style-type: none"> <li>• difficulty in swallowing</li> <li>• worsening of breathing problems (induced by the inhalation process). Inhaled medicines such as Spiriva may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation.</li> </ul>	<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>
<p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>● heartburn</li> </ul> <p><b>Bladder:</b></p> <ul style="list-style-type: none"> <li>● difficulty in passing urine</li> <li>● pain while passing urine, urinary tract infection, increased need and frequency in passing urine.</li> </ul>	

## **Very serious side effects**

<b>Very serious side effects</b>	<b>What to do</b>
<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, tongue or 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>● changes in heart rate (fast, slow or irregular)</li> </ul>	<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>

Very serious side effects	What to do
<ul style="list-style-type: none"> <li>● palpitations</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>	

**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 doctor's prescription.

## What Spiriva contains

<b>Active ingredient (main ingredient)</b>	tiotropium 18 micrograms (equivalent to tiotropium bromide monohydrate 22.5 micrograms)
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate (which contains milk protein)
<b>Potential allergens</b>	lactose

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

## What Spiriva looks like

Spiriva capsules (AUST R 81525) are light green with the product code "TI 01" and the Boehringer Ingelheim logo printed in black ink on the capsules.

Spiriva capsules contain a small amount of white powder, which means that the capsule is only partially filled. The amount of powder in each capsule is equivalent in size to the tip of a matchstick.

Spiriva is available in cartons containing 10\*, 30 or 60\* capsules and hospital packs containing 150\* or 300\* capsules. Combination packs of 10, 30\* and 150\* capsules with the HandiHaler device are also available.

\*Not currently distributed in Australia.

The HandiHaler device is available separately from your pharmacist and should be replaced every twelve months.

## **Who distributes Spiriva**

Spiriva is distributed in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

[www.boehringer-ingelheim.com.au](http://www.boehringer-ingelheim.com.au)

This leaflet was prepared in June 2021.

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