

# Spiriva® Powder for Inhalation

Tiotropium bromide

---

## What is in this leaflet

---

This leaflet answers some common questions about **Spiriva** capsules. It does not contain all available information. Nor does it take the place of talking to your doctor or pharmacist.

**Keep this information with your capsules.** You may need to read it again later.

### *To find out more about Spiriva*

**You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using Spiriva.**

---

## What Spiriva is used for

---

**Spiriva** is used to make breathing easier for people with conditions such as chronic obstructive pulmonary disease (COPD), bronchitis and emphysema. This helps to improve your condition and to prevent exacerbations (periodic worsening of symptoms) from occurring.

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

**Spiriva** contains the active ingredient tiotropium bromide. This medicine is known as an anticholinergic medicine.

---

## Before you use Spiriva

---

### *When you must not use Spiriva*

**Only use Spiriva if it has been prescribed for you by a doctor.**

Never give it to someone else even if their symptoms seem to be the same as yours.

**Do not use Spiriva if you are allergic to it or to any of the ingredients.**

These ingredients are listed in full at the end of this leaflet.

In some cases you should not use **Spiriva** if you are allergic to certain other medicines.

You must tell your doctor if you are allergic to atropine or any other anticholinergic medicines.

If you are uncertain as to whether you have these allergies you should raise your concerns with your doctor.

**You should never use Spiriva after the EXPIRY DATE on the blister strips or carton.**

### *Before you start to use Spiriva*

It is essential that your doctor knows your medical history before prescribing **Spiriva**.

**Before using Spiriva, you must tell your doctor if you have, or have had, any of the following conditions:**

- high pressure in the eye (glaucoma)
- kidney problems
- problems with your prostate gland
- problems with passing urine

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

**Before taking Spiriva you must tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription.**

In particular you must tell your doctor if you are taking other anticholinergic medicines such as ipratropium.

### ***Pregnancy***

**Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.**

**Spiriva** is not generally recommended for use in pregnant women, unless the benefits of treatment outweigh the risk to the unborn baby.

### ***Breastfeeding***

**Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication.**

It is not known whether **Spiriva** passes into breast milk. Your doctor will discuss the risks and benefits of using **Spiriva** if you intend to breastfeed.

### ***Children***

**Spiriva** is not recommended for use in children.

---

## **Using Spiriva**

---

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

**The powder in the capsules must only be inhaled using a HandiHaler device.**

**Use each strip of 5 capsules within 5 days of first opening the strip.**

**Please read the Directions for use at the end of this CMI for instructions on how to use Spiriva capsules with the HandiHaler device.**

**Follow the Directions for Use carefully. Using the HandiHaler device, pierce the capsule only once. If you pierce it more often, 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.**

**If you have any problems with inhaling Spiriva ask your doctor or pharmacist for advice.**

**Never allow Spiriva powder to come into contact with your eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes.**

### ***Recommended Dose***

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

### ***If you forget to take a dose***

**It is important to use Spiriva as directed.**

If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time.

**Do not take a double dose to make up for the dose that you missed.**

### ***How long to take Spiriva***

**Spiriva** helps control your condition, but does not cure it. Therefore you must use **Spiriva** every day. Continue using the medicine for as long as your doctor or pharmacist tells you.

**Do not stop using it unless your doctor or pharmacist tells you to – even if you feel better.**

### ***Overdose***

**Seek medical advice if you have used more than the recommended or prescribed dose of Spiriva and you experience signs of overdose as listed below.**

Advice can be provided by a doctor, pharmacist or Poisons Information Centre 0800 POISON (0800 764766).

Signs of overdose may include fast or irregular heart beat, blurred vision, nausea, stomach pain, dry mouth, constipation and difficulty passing urine.

---

## **While you are using Spiriva**

---

### ***Things you must do***

**It is very important to follow the Directions for Use carefully and avoid contact of the powder with the eyes.**

**Contact your doctor immediately if you experience eye pain or discomfort, or any disturbances with your sight (blurred vision, visual halos or coloured images) during or after using Spiriva.** This is because there have been isolated reports of narrow-angle glaucoma with the use of **Spiriva**.

**If your breathing becomes more difficult while you are using Spiriva, tell your doctor immediately.**

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

**Tell your doctor or pharmacist if you begin taking any other medicine while you are using Spiriva.** This applies to all medicines obtained with or without a doctor's prescription.

### ***Effects on ability to drive or operate machinery***

It is advisable to be careful when driving or operating machinery until you know how **Spiriva** affects you.

When taken as recommended, and when there are no side effects, **Spiriva** is not known to have any effect on the ability to drive or operate machinery.

---

## **Side effects**

---

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of you taking **Spiriva** against the benefits they expect it will have for you.

**Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.**

The more frequently reported side effects of **Spiriva** are:

- dry mouth
- dry throat
- cough
- fast heart beat
- blurred vision
- high pressure in the eye (glaucoma)
- oral candida (thrush)

Less frequently reported side effects of **Spiriva** include:

- constipation
- reflux
- difficulty in passing urine
- urinary tract infection
- itching, skin rash or allergic reactions (swollen tongue and lips, mouth ulcers and rash on the face).
- a change in heart rate
- hoarse voice

- nose bleeds

Dizziness has also been reported.

As with other inhaled medicines, a worsening of breathing problems (induced by the inhalation process) may occur.

**Tell your doctor as soon as possible if you experience any side effects during or after using Spiriva, so that these may be properly treated.**

In addition, unexpected effects, not listed above, can occur with any medicine.

**You should tell your doctor or pharmacist if you notice anything unusual, during or after using Spiriva.**

---

## After using Spiriva

---

### *Care and cleaning*

Follow the instructions under the heading **Directions for Use** at the end of this leaflet.

### *Storage*

Spiriva should be kept in a cool, dry place where the temperature stays below 25°C.

**Do not store Spiriva in the bathroom or near the sink.**

**Do not leave Spiriva in the car or on window sills.** Heat and dampness can destroy this medicine.

**Do not store Spiriva in the freezer.**

**Keep your Spiriva capsules where children cannot reach them.**

### *Disposal*

If your doctor tells you that you will not be needing **Spiriva** anymore, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

---

## Product Description

---

### *What Spiriva is*

**Spiriva** is the brand name of your medicine. It comes as a powder inside a capsule. You must use the HandiHaler device in order to inhale powder from the capsule.

**Spiriva** capsules contain a white powder. **Spiriva** capsules are light green with the product code "T1 01" and the Boehringer Ingelheim logo printed in black ink on the capsules.

**Spiriva** also contains lactose.

### *Ingredients*

Each capsule of **Spiriva** contains tiotropium 18 micrograms (equivalent to tiotropium bromide monohydrate 22.5 micrograms).

**Spiriva** also contains lactose.

### *Manufacturer*

**Spiriva** is supplied in New Zealand by:

BOEHRINGER INGELHEIM (N.Z.) LIMITED  
Level 1, 42 Ormiston Road, East Tamaki, Auckland  
Telephone (09) 274-8664 or 0800 802 461

or

Pfizer Pharmaceuticals Group  
Level 3 Pfizer House  
14 Normanby Rd, Mt Eden  
Auckland  
Tel: 09 638 0000

**This leaflet was prepared on 2 November 2007.**

Spiriva® is a registered trade mark of Boehringer Ingelheim

© Boehringer Ingelheim (N.Z.) Limited 2007