

Spiolto[®] Respimat[®]

2.5 micrograms/ 2.5 micrograms Solution for Inhalation

Tiotropium (as bromide monohydrate)/Olodaterol (as hydrochloride)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Spiolto Respimat.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Spiolto Respimat against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with the medicine.

You may need to read it again.

What Spiolto Respimat is used for

Spiolto Respimat is used for the treatment of Chronic Obstructive Pulmonary Disease, also called 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.

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 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.

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

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.

Spiolto Respimat is for oral inhalation only. The solution for inhalation is contained in the Spiolto Respimat cartridge and inhaled using the Spiolto Respimat inhaler supplied with the medicine.

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you use Spiolto Respimat

When you must not use it

Do not use Spiolto Respimat if you have an allergy to:

- any medicine containing tiotropium bromide or olodaterol hydrochloride (the active ingredients)
- any of the ingredients listed at the end of this leaflet
- any medicine containing atropine or its derivatives, e.g. ipratropium or oxitropium
- any other anticholinergic medicines.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing.

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.

Do not use Spiolto Respimat to treat asthma.

Safety and effectiveness in the treatment of asthma has not been established.

Do not use Spiolto Respimat to relieve an acute attack of breathlessness or wheezing.

Spiolto Respimat should only be used for maintenance treatment of your COPD.

Do not use this medicine after the expiry date printed on the inhaler label or carton, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

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

Tell your doctor if you have, or have had, any of the following medical conditions:

- asthma (you should not use Spiolto Respimat for the treatment of 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell him/her before you start using Spiolto Respimat.

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.

Use this medicine only with the Respimat device.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you get 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 or MAO inhibitors.

These medicines may be affected by Spiolto Respimat or may affect how well it works. You may need to take different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Spiolto Respimat

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to use

Take 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.

How to use it

Spiolto Respimat is for inhalation use only.

Make sure that you know how to use your Spiolto Respimat inhaler properly.

The instructions for use are provided at the end of this leaflet.

Carefully read the instructions for use and follow the diagrams that

show you how to use the Spiolto Respimat inhaler.

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

Use the Spiolto Respimat 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 inhaler to prepare the inhaler for first use.

The Spiolto Respimat 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.

When to use it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to use it

Continue to use Spiolto Respimat for as long as your doctor tells you.

This medicine helps to control your condition but it does not cure it. Therefore you must use Spiolto Respimat every day. It is important to keep taking your medicine even if you feel well.

If you forget to use it

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre 13 11 26 for advice, or go to Emergency at your nearest hospital, if you think that you or anyone else may have used too much Spiolto Respimat. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- 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 spasm
- 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.

While you are using Spiolto Respimat

Things you must 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.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using Spiolto Respimat.

Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are a smoker, you should stop smoking.

Your doctor or pharmacist can advise you on the steps to take to quit smoking.

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.

Things you must not do

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 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 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.

Things to be careful of

Be careful driving or operating machinery until you know how Spiolto 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Spiolto Respimat.

This medicine helps most people with COPD, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- runny nose or nose bleeds
- 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

- dry or sore mouth or throat and discomfort when swallowing; swollen, red, sore tongue; gingivitis or tooth decay
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- sore, creamy-yellow, raised patches in the mouth or throat (thrush)
- hoarse voice
- a change in bowel movements, e.g. constipation
- a burning sensation in the chest rising up to the throat, also known as heartburn
- difficulty passing urine
- symptoms of urinary tract infection such as a frequent need to urinate, only passing a few drops, burning pain or a 'scalding' sensation when urinating, feeling that the bladder is still full after urinating, pain above the pubic bone or blood in the urine
- headache
- dizziness
- trouble sleeping
- blurred vision
- dehydration
- back or joint pain, joint swelling
- shortness of breath, cough, or chest infections
- rash or dry skin; skin infection or skin ulcer.

Tell your doctor as soon as possible if you notice any symptoms that may indicate the level of potassium in your blood is low such as muscle spasm, muscle weakness or abnormal heart rhythm.

These may be serious side effects that may require medical attention.

If any of the following happen, stop using the medicine and tell your doctor immediately or go to

Emergency at your nearest hospital:

- allergic reaction (shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing; swelling of other parts of the body, rash, itching or hives on the skin)
- any side effects affecting your heart (such as fast or irregular heartbeats, palpitations, increase or decrease in blood pressure and/or increase in symptoms like chest pain)
- severe pain in the stomach with bloating, gut cramps and vomiting.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

You may also experience side effects which are known to occur with certain similar medicines for breathing problems. These may include changes in heart rate (fast, slow or irregular), chest pain (angina pectoris), high or low blood pressure, shaking, nervousness, nausea, muscle spasm, fatigue, generally feeling unwell; passing large amounts of urine, excessive thirst and having a dry mouth and skin (symptoms of too much sugar in the blood); and increased rate of breathing.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Spiolto Respimat

Care and cleaning

Follow the instructions at the end of this leaflet 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.

Storage

Keep Spiolto Respimat in a cool dry place where the temperature stays below 30°C. Do not freeze.

Do not store Spiolto Respimat or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Discard Spiolto Respimat inhaler 3 months after inserting the Spiolto Respimat cartridge into the Spiolto Respimat inhaler even if it contains some unused medicine, or when the inhaler is locked (after 60 puffs), whichever comes first.

Disposal

If your doctor tells you to stop using this medicine, or the expiry date has passed, or it has been more than 3 months after its first use, or if the inhaler has locked (after 60 puffs), ask your pharmacist how to dispose of it properly.

Product Description

What it looks like

Spiolto Respimat is available as a solution for inhalation contained in the cartridge. The Spiolto Respimat inhaler (with a light-green coloured

cap) enables you to inhale the medicine from the cartridge.

Each pack consists of:

- one Spiolto Respimat cartridge containing the solution for inhalation and
- one Spiolto Respimat inhaler providing 60 puffs (equal to 30 doses of medicine).

Ingredients

Spiolto Respimat contains 2.5 micrograms tiotropium (as bromide monohydrate) and 2.5 micrograms olodaterol (as hydrochloride) per puff.

It also contains:

- benzalkonium chloride
- disodium edetate
- hydrochloric acid
- purified water.

Supplier

Spiolto Respimat is supplied in Australia by:

Boehringer Ingelheim Pty Limited
ABN 52 000 452 308
78 Waterloo Road
NORTH RYDE NSW 2113

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Australian Registration Number

AUST R 226452

Spiolto[®] Respimat[®]

2.5 micrograms/ 2.5 micrograms Solution for Inhalation

Tiotropium (as bromide monohydrate)/Olodaterol (as hydrochloride)

Instructions for Use

Introduction

Read these Instructions for Use before you start using Spiolto Respimat (tiotropium bromide monohydrate and olodaterol hydrochloride).

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



How to store my Spiolto Respimat

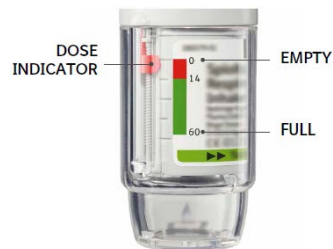
- Keep your Spiolto Respimat out of the sight and reach of children.
- Do not freeze your Spiolto Respimat.
- If Spiolto Respimat has not been used for more than 7 days release one puff towards the ground.
- If Spiolto Respimat has not been used for more than 21 days repeat steps 4 to 6 under 'Prepare for first use' until a cloud is visible. Then repeat steps 4 to 6 three more times.
- Do not use your Spiolto Respimat after the expiry date.
- Do not touch the piercing element inside the clear base.

How to care for 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.

Any minor discoloration in the mouthpiece does not affect your Spiolto Respimat inhaler performance.

When to get a new Spiolto Respimat



- Your Spiolto Respimat inhaler contains 60 puffs (30 doses) if used as indicated (two puffs/once daily).
- The dose indicator shows approximately how much medication is left.
- When the dose indicator enters the red area of the scale you need to get a new prescription; there is approximately medication for 7 days left (14 puffs).
- Once the dose indicator reaches the end of the red scale, your Spiolto Respimat locks automatically – no more doses can be released. At this point, the clear base cannot be turned any further.
- Three months after first use, the Spiolto Respimat should be discarded even if it has not been used.

Prepare for first use

1. Remove clear base

- Keep the cap closed.
- Press the safety catch while firmly pulling off the clear base with your other hand.



2. Insert cartridge

- Insert the narrow end of the cartridge into the inhaler.
- Place the inhaler on a firm surface and push down firmly until it snaps into place.



3. Replace clear base

- Put the clear base back into place until it clicks.



4. Turn

- Keep the cap closed.
- Turn the clear base in the direction of the arrows on the label until it clicks (half a turn).



5. Open

- Open the cap until it snaps fully open.



6. Press

- 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.**



PRESS

- Breathe out slowly and fully.
- Close your lips around the mouthpiece without covering the air vents.
- While taking a slow, deep breath through your mouth, PRESS the dose-release button and continue to breathe in.
- Hold your breath for 10 seconds or for as long as comfortable.
- Repeat Turn, Open, Press for a total of 2 puffs.



Daily use

TURN

- Keep the cap closed.
- TURN the clear base in the direction of the arrows on the label until it clicks (half a turn).



OPEN

- OPEN the cap until it snaps fully open.

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.

Did you insert the cartridge with the wide end first?

Insert the cartridge with the narrow end first.

Did you place the inhaler on a firm surface and push down firmly until the cartridge snaps into place?

The cartridge should be pushed firmly against a firm surface to ensure that it has gone all the way in. The cartridge will not be flush with the inhaler, you will see the silver ring of the lower end of the cartridge.

I cannot press the dose-release button

Did you turn the clear base?

If not, turn the clear base in a continuous movement until it clicks (half a turn).

Is the dose indicator on the Spiolto Respimat pointing to zero?

The Spiolto Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Spiolto Respimat inhaler.

I cannot turn the clear base

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.

Is the dose indicator on the Spiolto Respimat pointing to zero?

The Spiolto Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Spiolto Respimat inhaler.

The dose indicator on the Spiolto Respimat reaches zero too soon

Did you use Spiolto Respimat as indicated (two puffs/once daily)?

Spiolto Respimat will last 30 days if used at two puffs once daily.

Did you turn the clear base before you inserted the cartridge?

The dose indicator counts each turn of the clear base regardless whether a cartridge has been inserted or not.

Did you spray in the air often to check whether the Spiolto Respimat is working?

Once you have prepared Spiolto Respimat, no test-spraying is required if used daily.

Did you insert the cartridge into a used Spiolto Respimat inhaler?

Always insert a new cartridge into a NEW Spiolto Respimat inhaler.

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).

My Spiolto Respimat doesn't spray

Did you insert a cartridge?

If not, insert a cartridge.

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 first use”.

Is the dose indicator on the Spiolto Respimat pointing to 0?

If the dose indicator points to 0, you have used up all your medication and the inhaler is locked.

Once your Spiolto Respimat is assembled, do not remove the clear base or the cartridge. Always insert a new cartridge into a NEW Spiolto Respimat inhaler.

Supplier

Spiolto Respimat inhaler is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

78 Waterloo Road

NORTH RYDE NSW 2113

Manufacturer

Spiolto Respimat inhaler is manufactured by:

Boehringer Ingelheim Pharma GmbH & Co. KG

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D-55216 Ingelheim am Rhein

Germany

CE 0123