

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 re-usable 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 Spiolto Respimat re-usable inhaler.

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 re-usable inhaler properly.

Refer to the Respimat re-usable inhaler Instructions for Use.

Carefully read the Instructions for Use and follow the diagrams that show you how to use the Spiolto Respimat re-usable inhaler.

Scan the QR code provided at the end of this leaflet for a video demonstration.

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

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.

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

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.

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.

Exchange 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 inhaler.

Disposal

If your doctor tells you to stop using this medicine, or the expiry date has passed, 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 re-usable inhaler (with a light-green coloured cap) enables you to inhale the medicine from the cartridge.

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

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.

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

Sydney, Australia

www.boehringer-ingelheim.com.au

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