

SPIOLTO RESPIMAT

INHALATION SOLUTION

Tiotropium/olodaterol (2.5 microgram/ 2.5 microgram per actuation)

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What SPIOLTO RESPIMAT is used for

SPIOLTO RESPIMAT helps adult patients who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a long-term lung disease that causes shortness of breath and coughing. The term COPD is associated with the condition's chronic bronchitis and emphysema.

How SPIOLTO RESPIMAT works

SPIOLTO RESPIMAT helps to open your airways and make it easier to get air in and out of the lungs. Regular use of SPIOLTO RESPIMAT can also help you when you have on-going shortness of breath related to your disease, and will help to minimise the effects of the disease on your everyday life. As COPD is a long-term disease you should take SPIOLTO RESPIMAT every day and not only when you have breathing problems or other symptoms of COPD.

Before you use SPIOLTO RESPIMAT

- When you must not use it

Do not use SPIOLTO RESPIMAT

- if you are allergic to tiotropium or olodaterol or any of the other ingredients of this medicine (listed in Product Description)
- if you are allergic to atropine or substances related to it, e.g. ipratropium or oxitropium

SPIOLTO RESPIMAT should not be given to children or adolescents (below the age of 18 years).

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not use this medicine unless specifically recommended by your doctor.

This medicine contains 0.0011 mg benzalkonium chloride in each actuation.

Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

- Before you start use it

Talk to your doctor or pharmacist before using SPIOLTO RESPIMAT

- if you have asthma (you should not use SPIOLTO RESPIMAT for the treatment of asthma).
- if you have diseases of the heart.
- if you have high blood pressure.
- if you have epilepsy.
- if you have a specific thyroid gland problem called thyrotoxicosis.
- if you have an abnormal widening of an artery called aneurysm.
- if you have diabetes.
- if you have severe hepatic (liver) disease.
- if you have renal (kidney) disease.
- in case of a planned surgery.
- if you have an eye problem called narrow-angle glaucoma.
- if you have prostate problems or have difficulty passing urine.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines.

In particular, please tell your doctor if you are using:

- any medicines that may be similar to SPIOLTO RESPIMAT (contain similar active substances, such as anticholinergic drugs or β -adrenergic

agents). You may be more likely to get side effects.

- medicines called beta blockers that are used for high blood pressure or other heart problems (such as propranolol), or for the eye problem called glaucoma (such as timolol). This may result in loss of the effect of SPIOLTO RESPIMAT.
- medicines that lower the amount of potassium in your blood. These include:
 - steroids (e.g. prednisolone),
 - diuretics (water tablets),
 - medicines for breathing problems such as theophylline.

If you use these medicines together with SPIOLTO RESPIMAT you may experience symptoms of muscle spasm, muscle weakness or abnormal heart rhythm.

- medicines called tricyclic antidepressants or monoamine oxidase (MAO) inhibitors (like selegiline or moclobemide), that are used to treat neurological or psychiatric disorders like Parkinson's disease or depression; the use of these drugs will increase the likelihood that you get side effects affecting your heart.

How to use SPIOLTO RESPIMAT

SPIOLTO RESPIMAT is for inhalation use only.

Make sure that you know how to use your SPIOLTO RESPIMAT inhaler properly. The Handling Instructions of the SPIOLTO RESPIMAT inhaler are provided in this leaflet.

- How much to use

The recommended dose is:

Each time you use it take TWO PUFFS.

- When to use it

SPIOLTO RESPIMAT is effective for 24 hours so you will need to use SPIOLTO RESPIMAT only ONCE A DAY, if possible, at the same time of the day.

- How long to use it

As COPD is a long-term disease take SPIOLTO RESPIMAT every day and not only when you experience breathing problems. Do not take more than the recommended dose.

Before you stop taking SPIOLTO RESPIMAT, you should talk to your doctor or your pharmacist. If you stop taking SPIOLTO RESPIMAT the signs and symptoms of COPD may worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

If you forget to inhale a dose, inhale just one dose at the usual time the next day.

- If you use too much (overdose)

You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, blurred vision, chest pain, high or low blood pressure, faster or irregular heartbeat or feeling of heart beat, dizziness, nervousness, difficulty in sleeping, anxiety, headache, shaking, muscle cramps, nausea, fatigue, malaise, low blood levels of potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm), high blood sugar, or too much acid in your blood (which may cause symptoms of nausea, vomiting, weakness, muscle cramps and more rapid breathing).

While you are using it

- Things you must do

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Things you must not do

SPIOLTO RESPIMAT is indicated for the maintenance treatment of your chronic obstructive pulmonary disease or asthma. Do not use this medicine to treat a sudden attack of breathlessness or wheezing.

Do not take SPIOLTO RESPIMAT more frequently than once daily.

- Things to be careful of

- Stop using the medicine and tell your doctor immediately if you get tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine. These may be signs of a condition called bronchospasm.
- If your breathing has got worse or if you experience rash, swelling or itching directly after using your inhaler, stop using it and tell your doctor immediately.
- If you experience any side effects affecting your heart (increase in pulse rate, increase in blood pressure and/or increase in symptoms like chest pain), tell your doctor immediately.
- If you experience muscle spasm, muscle weakness or abnormal heart rhythm, consult your doctor as these may be related to low blood levels of potassium.

When taking SPIOLTO RESPIMAT take care not to let any spray enter your eyes. This 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. Wash your eyes in warm water, stop using SPIOLTO RESPIMAT and immediately consult your doctor for further advice.

Do not use SPIOLTO RESPIMAT together with certain medicines containing long-acting β -adrenergic agonists, like salmeterol or formoterol.

If you regularly take certain medicines called short-acting β -adrenergic agents, like salbutamol, continue to use these only to relieve acute symptoms like breathlessness.

Dry mouth which has been observed with anti-cholinergic treatment may in the long term be associated with dental caries. Therefore, please remember to pay attention to oral hygiene.

No studies on the effects on the ability to drive and use machines have been performed.

If you feel dizzy or if blurred vision occurs while taking SPIOLTO RESPIMAT, do not drive or use any tools or machines.

Side effects

Like all medicines, SPIOLTO RESPIMAT can cause side effects, although not everybody gets them.

If any of the following occurs, please stop using this medicine and consult your doctor immediately.

- Immediate allergic reactions to SPIOLTO RESPIMAT are rare (they may affect up to 1 in 1,000 people). These reactions may occur individually or as part of a severe allergic reaction (anaphylactic reaction) after administration of SPIOLTO RESPIMAT. These include rash, nettle rash (urticaria), swelling of the mouth and face, sudden difficulties in breathing (angioneurotic oedema) or other hypersensitivity reactions (such as sudden reduction of your blood pressure or light headedness).
- As with all inhaled medications, tightness of the chest, associated with coughing, wheezing or breathlessness may occur immediately after inhalation (paradoxical bronchospasm). The frequency cannot be estimated from the available data.
- seeing halos around lights or coloured images in association with red eyes (glaucoma). The frequency cannot be estimated from the available data.
- blockage of intestines or absence of bowel movements (intestinal obstruction, including ileus paralytic). The frequency cannot be estimated from the available data.

Other possible side effects:

Uncommon (may affect up to 1 in 100 people)

- faster heart beat (tachycardia)
- dizziness
- headache
- cough
- dry mouth

Rare (may affect up to 1 in 1,000 people)

- hoarseness (dysphonia)
- irregular heart beat (atrial fibrillation)

- rapid heartbeat (supraventricular tachycardia)
- feeling your heartbeat (palpitations)
- high blood pressure (hypertension)
- difficulties passing urine (urinary retention)
- painful urination (dysuria)
- sore throat (pharyngitis)
- inflammation of the larynx (laryngitis)
- inflammation of the gums (gingivitis)
- inflammation of the mouth (stomatitis)
- fungal infections of the mouth and throat (oropharyngeal candidiasis)
- nosebleed (epistaxis)
- difficulty in sleeping (insomnia)
- blurred vision
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- constipation
- feeling sick (nausea)
- itching (pruritus)
- joint pain (arthralgia)
- swelling of joint
- back pain

Not known (frequency cannot be estimated from the available data)

- infections of the urinary tract
- increase of the measured eye pressure
- nasopharyngitis
- inflammation in sinuses (sinusitis)
- difficulties swallowing (dysphagia)
- inflammation of the tongue (glossitis)
- heart burn (gastroesophageal reflux disease)
- dental caries
- infections or ulcerations of the skin
- dryness of the skin
- depletion of body water (dehydration)

You may also experience side effects which are known to occur with certain medicines for breathing problems similar to SPIOLTO RESPIMAT (β-adrenergic agents). These may be irregular heartbeat, chest pain, low blood pressure, shaking, nervousness, muscle cramps, fatigue, malaise, low blood levels of potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm), high blood sugar, or too much acid in your blood (which may cause symptoms of nausea, vomiting,

weakness, muscle cramps and more rapid breathing).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SPIOLTO RESPIMAT

- Storage

Keep out of the reach and sight of children.

Store at or below 30°C. Do not freeze.

Exchange the cartridge latest three months after insertion.

Recommended use: 6 cartridges per inhaler

Note: The functioning of the Respimat re-usable inhaler has been demonstrated in tests for 540 actuations (corresponding to 9 cartridges).

- Disposal

Do not use SPIOLTO RESPIMAT after the expiry date which is stated on the carton and on the inhaler label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

SPIOLTO RESPIMAT is composed of one cartridge with inhalation solution and one Respimat inhaler. The cartridge has to be inserted into the inhaler before the first use.

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

Single refill pack: 1 cartridge, providing 60 puffs (30 medicinal doses)

- Ingredients

- Active ingredient:

The active substances are tiotropium and olodaterol. The delivered dose is 2.5 microgram tiotropium (as bromide monohydrate) and 2.5 microgram olodaterol (as hydrochloride) per puff. The delivered dose is the dose which is available for the patient after passing the mouthpiece.

- Inactive ingredients:

Benzalkonium chloride

Disodium edetate

Purified water

Hydrochloric acid for pH adjustment

- MAL number

MAL17075001AZ

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG

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for

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Product Registration Holder

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23/05/2025

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Internal reference only

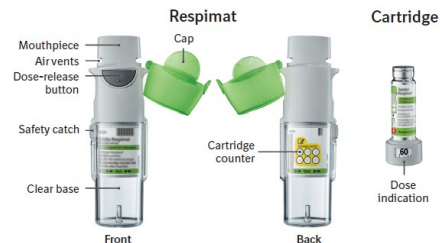
This PIL is drafted based on the SPIOLTO RESPIMAT MY Proposed PI dated 19-Jun-24.

SPIOLTO RESPIMAT re-usable**Handling Instructions**

Read these Handling Instructions before you start using SPIOLTO RESPIMAT re-usable.

You will need to use this inhaler only **ONCE A DAY**.

Each time you use it take **TWO PUFFS**.



If not been used for more than 7 days release one puff towards the ground.

If not been used for more than 21 days repeat steps 4 to 6 until a cloud is visible. Then repeat steps 4 to 6 three more times.

How to care for your SPIOLTO RESPIMAT re-usable

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 re-usable inhaler performance.

If necessary, wipe the outside of your SPIOLTO RESPIMAT re-usable inhaler with a damp cloth.

When to replace the inhaler

When you have used an inhaler with 6 cartridges, get a new SPIOLTO RESPIMAT re-usable pack containing an inhaler. Do not use the Respimat re-usable inhaler for more than one year, after having inserted the first cartridge.

**Prepare for use****1. Remove clear base**

Keep the cap closed.

Press the safety catch while pulling off the clear base with your other hand.

**2. Insert cartridge**

Insert the cartridge into the inhaler.

Place the inhaler on a firm surface and push down firmly until it clicks into place.

**3. Track cartridge and put clear base back**

Mark the check-box on inhaler's label to track the number of cartridges.

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.

Your inhaler is now ready to use and will deliver 60 puffs (30 doses).

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.**PRESS**

Breathe out slowly and fully.

Close your lips around the mouthpiece without covering the air vents. Point your Inhaler to the back of your throat.

While taking a slow, deep breath through your mouth, **PRESS** the dose-release button and continue to breathe in slowly for as long as comfortable.

Hold your breath for 10 seconds or for as long as comfortable.

Repeat Turn, Open, Press for a total of 2 puffs.

Close the cap until you use your inhaler again.

When to replace the SPIOLTO RESPIMAT Cartridge

The dose indicator shows how many puffs remain in the cartridge.



60 puffs remaining



Less than 10 puffs remaining. Obtain a new cartridge



Your cartridge is used up. Turn the clear base to loosen it. Your inhaler is now in a locked position. Pull off the cartridge from the inhaler. Insert a new cartridge until it clicks (refer to step 2 in 'Prepare for Use').

The new cartridge will stick out more than the very first cartridge (continue with step 3 in 'Prepare for Use').

Remember to put the clear base back to unlock the inhaler.

Answers to Common Questions

1. 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.
 - **Are you replacing the cartridge?** The new cartridge will stick out more than the very first cartridge. Insert it until it clicks, then replace the clear base.
2. I cannot press the dose release button.
 - **Did you put the clear base back?** If not, put the clear base back to unlock the inhaler. The Respimat re-usable only functions with the clear base in place.
 - **Did you turn the clear base?** If not, turn the clear base in a continuous movement until it clicks (half a turn).
 - **Does the dose indicator on your cartridge display a white arrow on a red background?** Your cartridge is used up. Insert a new cartridge.
3. It is difficult to remove the cartridge after it is used up.

Pull and turn the cartridge at the same time.
4. I cannot turn or replace the clear base back.

- **Is the clear base loose and does the dose indicator on your cartridge display a white arrow on a red background?** Your cartridge is used up. Insert a new cartridge.
 - **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.
5. My RESPIMAT re-usable has been used up too early.
 - **Did you use Respimat re-usable as indicated (two puffs/once daily)?** Respimat will last 30 days if used at two puffs once daily.
 - **Did you spray in the air often to check whether the Respimat re-usable is working?** Once you have prepared Respimat re-usable, no test-spraying is required if used daily.
 - **Did you take off and put the clear base multiple times back?** Do not remove the clear base before the cartridge is used up. Each time you take off the clear base without cartridge exchange, the dose counter records one puff and the remaining doses are reduced.
 6. My Respimat re-usable doesn't spray.
 - **Did you insert a cartridge?** If not, insert a cartridge. If not, insert a cartridge. Once your RESPIMAT re-usable is assembled, do not remove the clear base or the cartridge until the cartridge is used up.
 - **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 use".
 - **Does the dose indicator on your cartridge display a white arrow on a red background?** Your cartridge is used up. Insert a new cartridge.
 7. My RESPIMAT re-usable 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). The dose counter will count each incomplete turn and the number of remaining doses is reduced.
- **Was the cap open when you replaced the cartridge?** Close the cap, then replace the cartridge.