

SPIRIVA RESPIMAT

SOLUTION FOR INHALATION

Consumer Medication Information Leaflet (RiMUP)

Tiotropium (2.5 microgram)

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What SPIRIVA RESPIMAT is used for

SPIRIVA RESPIMAT helps people who have chronic obstructive pulmonary disease (COPD) or asthma 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 inflammation of the mucous membrane in the airway tubes and the condition in which the air sacs of the lungs are damaged and enlarged, causing breathlessness. Asthma is a long-term disease characterised by airway inflammation and narrowing of the airways. When used to treat asthma you should use SPIRIVA RESPIMAT as add-on maintenance for patients aged 6 years and above with severe condition.

How SPIRIVA RESPIMAT works

SPIRIVA RESPIMAT is a long-acting bronchodilator that helps to open your airways and makes it easier to get air in and out of the lungs. Regular use of SPIRIVA 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. Daily use of SPIRIVA RESPIMAT will also help to prevent any sudden, short-term worsening of your COPD symptoms which may last for several days.

For correct dosing of SPIRIVA RESPIMAT please see Section 4. How to use SPIRIVA RESPIMAT and the

Handling Instructions provided on the other side of the leaflet.

Before you use SPIRIVA RESPIMAT

- When you must not use it

You should not use SPIRIVA RESPIMAT if you are allergic (hypersensitive) to tiotropium, its active ingredient or inactive ingredients listed under Section 8. Product Description.

You should not use SPIRIVA RESPIMAT if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium.

You should not use SPIRIVA RESPIMAT on infants or children below 6 years old.

Do not take SPIRIVA RESPIMAT if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take SPIRIVA RESPIMAT if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

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

Before you use SPIRIVA RESPIMAT, talk to your doctor or pharmacist if you:

- are suffering from seeing halos around lights or coloured images in association with red eyes, enlarged prostate or bladder-neck obstruction (have difficulty passing urine)
- have any kidney problems

- Taking other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those not prescribed.

Please tell your doctor or pharmacist if you are taking/have taken similar medicines for your lung disease, such as ipratropium or oxitropium.

No interaction side effects have been reported when SPIRIVA RESPIMAT has been taken together with other products used to treat COPD and asthma.

How to use SPIRIVA RESPIMAT

SPIRIVA RESPIMAT is for inhalation use only.

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

If you have any problems using SPIRIVA RESPIMAT, ask your doctor, nurse or pharmacist to show you how it works.

- How much to use

The recommended dose for patients 6 years and older is:
Each time you use it take TWO PUFFS.

- When to use it

Always take this medicine exactly as your doctor has told you.

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

Check with your doctor or pharmacist if you are not sure.

- How long to use it

As COPD and asthma are long-term diseases, take SPIRIVA RESPIMAT every day and not only when you experience breathing problems. Do not take more than the recommended dose.

Before you stop taking SPIRIVA RESPIMAT, you should talk to your doctor or your pharmacist.

If you stop taking SPIRIVA RESPIMAT, the signs and symptoms of COPD may worsen.

- If you forget to use it

If you forget to take a dose (TWO PUFFS ONCE A DAY), take one as soon as you remember but do not take two doses at the same time or on the same day. Then take your next dose as usual.

- If you use too much (overdose)

If you take more SPIRIVA RESPIMAT than two puffs in one day, you should talk to your doctor immediately. You may be at a higher risk of experiencing a side effect such as dry mouth or throat.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

If you have been prescribed SPIRIVA RESPIMAT for your asthma it should be added on to inhaled corticosteroids and long-acting β_2 agonists. Continue taking the inhaled corticosteroids as prescribed by your doctor, even if you feel better.

- Things you must not do

SPIRIVA 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 any new medicines without consulting your doctor or pharmacist.

Do not take SPIRIVA RESPIMAT more frequently than once daily.

Do not touch the piercing element inside the base.

- Things to be careful of

When taking SPIRIVA RESPIMAT, take care not to let any of the 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). Wash your eyes in warm water immediately, stop using tiotropium bromide and talk to your doctor immediately for further advice.

If you feel that 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.

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

This medicine may affect your ability to drive or use machines. If you feel sick, dizziness, blurred vision, or headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, SPIRIVA RESPIMAT can cause side effects, although not everybody gets them. The side effects described below have been experienced by people taking this medicine.

Metabolism and nutrition disorders:

dehydration

Nervous system disorders:

dizziness
difficulty in sleeping

Eye disorders:

seeing halos around lights or coloured images in association with red eyes
pressure within the eye increased
vision blurred

Cardiac disorders:

irregular heartbeat
feeling your heartbeat
faster heart beat

Respiratory, thoracic and mediastinal disorders:

cough
nosebleed
inflammation of the throat
speech disturbance resulting in a hoarse voice

associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
inflammation of the larynx/voice box
inflammation of the sinuses

Gastro-intestinal disorders:

dry mouth, usually mild
constipation
fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
difficulties swallowing
heart burn (gastroesophageal reflux disease)
inflammation of the gums
inflammation of the tongue
inflammation of the mouth
blockage of intestines or absence of bowel movements

Skin and subcutaneous tissue disorders:

Immune system disorders:

rash
itching
swelling of the face or throat (angioedema)
nettle rash
skin infection and skin ulcer
dry skin
hypersensitivity (including immediate reactions)

Musculoskeletal and connective tissue disorders:

joint swelling

Renal and urinary disorders:

urinary retention (usually in men with predisposing factors)
painful urination (dysuria)
urinary tract infection

The frequency, type, and severity of adverse reactions in the children population are similar as in adults.

If any of the side effects gets serious or, if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 SPIRIVA RESPIMAT**- Storage**

Keep out of the reach and sight of children.

Do not store above 30°C

Do not freeze.

Exchange the cartridge latest three months after insertion.

Do not use the Respimat re-usable inhaler for more than one year.

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 SPIRIVA 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.

Medicines should not be disposed of 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**

SPIRIVA RESPIMAT 2.5 microgram 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:**

Tiotropium bromide

The delivered dose is 2.5 microgram tiotropium per puff (2 puffs comprise one medicinal dose) and is equivalent to 3.124 microgram tiotropium bromide monohydrate. The delivered dose is the dose which is available for you after passing the mouthpiece.

- Inactive ingredients:
Benzalkonium chloride
Disodium edetate
Purified water
Hydrochloric acid 3.6% for pH adjustment

- MAL number

MAL25016003ASZ

Manufacturer

Boehringer Ingelheim España, S.A.

c/ Prat de la Riba, 50

08174 Sant Cugat del Vallès

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for

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Product Registration Holder

Boehringer Ingelheim (Malaysia) Sdn. Bhd.

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Date of revision

24/02/2025

Serial Number

NPRA (R1) 24/018

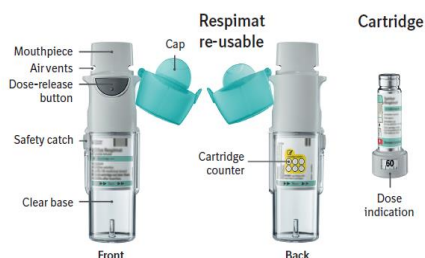
SPIRIVA RESPIMAT re-usable**Handling Instructions**

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

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

Each time you use it take TWO PUFFS.

Children should use SPIRIVA RESPIMAT re-usable with an adult's assistance.



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 SPIRIVA 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 SPIRIVA RESPIMAT re-usable inhaler performance. If necessary, wipe the outside of your SPIRIVA 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 SPIRIVA 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. Repeat Turn, Open, Press for a total of 2 puffs.

Close the cap until you use your inhaler again.

When to replace the Spiriva 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 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 reusable only functions with the clear base in place.

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- **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.