

SPIRIVA RESPIMAT

SOLUTION FOR INHALATION

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 in addition to so-called inhaled corticosteroids and long-acting β_2 agonists and you experienced one or more severe exacerbations in the previous year.

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. How to use Spiriva Respimat and the instructions for use 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 ingredient listed under section 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 and adolescents below 18 years.

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.

- 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.

The instructions for use of the Spiriva Respimat inhaler are provided on the other side 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 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 your daily dose, 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 SPIRIVA RESPIMAT

- 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.

The Spiriva Respimat inhaler must not be disassembled after inserting the cartridge and replacing the clear base.

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 powder 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), you should wash your eyes in warm water immediately. Then talk to your doctor immediately for further information.

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 heart beat
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

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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems/Side Effects/AEFI / Vaccine Safety).

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.
Spiriva Respimat inhaler should be discarded at the latest 3 months after first use.

- Disposal

Do not use SPIRIVA RESPIMAT after the expiry date which is stated on the

carton and the blister foil. The expiry date refers to the last day of that month.

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Malaysia

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.

Date of revision

02/10/2017

Serial Number

NPRA(R4/1)210917/00255

Product Description

- *What it looks like*

SPIRIVA RESPIMAT 2.5 microgram is composed of one 4.5ml 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 inhaler and 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*

MAL20091850AZ

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG

Ingelheim am Rhein

Germany

for

Boehringer Ingelheim International

GmbH

Ingelheim am Rhein

Product Registration Holder

Boehringer Ingelheim (Malaysia) Sdn.

Bhd.

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No. 6 Jalan Changkat Semantan

Damansara Heights

INSTRUCTIONS FOR USE

Spiriva Respimat, Inhalation for Solution

Remember to carefully follow your doctor’s instructions for using SPIRIVA RESPIMAT.

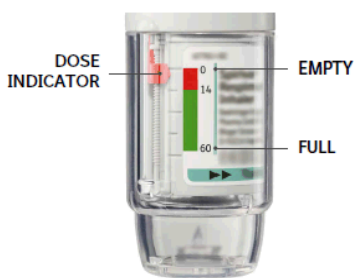


How to care for your SPIRIVA RESPIMAT

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 SPIRIVA RESPIMAT inhaler performance.

When to get a new SPIRIVA RESPIMAT



- Your SPIRIVA 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 SPIRIVA 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 SPIRIVA 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. The cartridge will not be hidden within the inhaler, you will still see the silver ring of the lower end of the cartridge. Do not remove the cartridge once it has been inserted into the inhaler.



3. Replace clear base

Do not remove the clear base again.



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. If Spiriva Respimat inhaler has not been used for more than 7 days release one puff towards the ground. If Spiriva Respimat inhaler has not been used for more than 21 days repeat steps 4 to 6.

Daily use



TURN

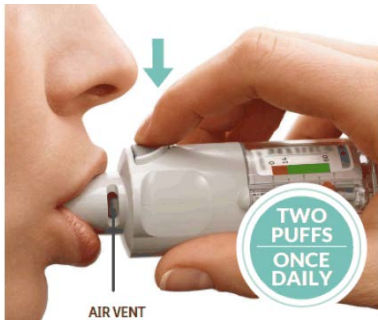
Keep the cap closed

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.

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.