

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is to be supplied upon physician's prescription only

Spiriva[®] Respimat[®] Solution for inhalation

Each actuation releases: 2.5 microgram tiotropium (as bromide monohydrate)

2 puffs, which comprise one therapeutic dose, contain: 5 microgram tiotropium (as bromide monohydrate)

Inactive ingredients and allergens in this medicine: See section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your physician or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

COPD

Spiriva Respimat is intended for maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease (COPD).

Asthma

Spiriva Respimat is indicated for maintenance treatment in children over 6 years old and in adults with severe asthma who experienced at least one severe exacerbation during the past year.

Therapeutic group: anticholinergic agents.

More information about this medicine

Spiriva Respimat helps patients with COPD or asthma to breathe more easily. COPD is a chronic lung disease causing shortness of breath and cough. COPD is a condition associated with chronic inflammatory states of the airways (bronchitis) and emphysema. Asthma is a chronic disease associated with airway inflammation and narrowing of the airways. Since COPD and asthma are chronic diseases, you must take Spiriva Respimat every day, and not only when you experience breathing problems or other symptoms. When used to treat asthma, you should use Spiriva Respimat in addition to medications called inhaled corticosteroids and long-acting β_2 -agonists.

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 may help you when you suffer from shortness of breath resulting from your illness, and will also help to minimize 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 dosage, see section 3. How it should be taken and the instructions for use are listed at the end of this leaflet.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient tiotropium or to any of the other ingredients that this medicine contains (see section 6 for the list of inactive ingredients).
- You are sensitive (allergic) to atropine or to other similar substances, such as ipratropium or oxitropium.

Special warnings regarding use of the medicine

Before using Spiriva Respimat, tell your physician if:

- You have narrow-angle glaucoma.
- You have prostate problems or difficulty passing urine.
- You have kidney problems.
- Avoid contact of the medicine with the eyes, since this may cause eye pain or discomfort, blurred vision, seeing halos around lights or colored images in association with red eyes (i.e. narrow-angle glaucoma). Eye symptoms may be accompanied by headache, nausea or vomiting. Immediately wash your eyes in warm water, stop using Spiriva Respimat and consult your physician immediately.
- Your breathing gets worse, or if you experience rash, swelling or itching immediately after using your inhaler, stop using the medicine and consult your physician immediately.
- Dry mouth, which may occur during treatment with anticholinergic medicines (medicines in the same group as tiotropium bromide), may, in the long term, cause dental caries, therefore oral hygiene must be strictly maintained.
- Spiriva Respimat is indicated for maintenance treatment of your chronic obstructive pulmonary disease or asthma. Do not use this medicine to treat a sudden attack of breathlessness or wheezing. Your physician should have given you another inhaler ("rescue medication") for this. Please follow the instructions your physician has given you.
- When used to treat asthma, Spiriva Respimat is added on to your existing treatments that include inhaled corticosteroids and long-acting β_2 agonists. Continue taking the inhaled corticosteroid as prescribed by your physician, even if your condition improves.
- You have had a heart attack during the past 6 months, or have had unstable or life threateningly irregular heartbeat, or severe heart failure within the past year. This information is important in deciding whether Spiriva Respimat is the right medicine for you.
- Do not take this medicine more than once a day.
- Consult your physician if you feel that your breathing is getting worse.
- You have cystic fibrosis; Spiriva Respimat could make your cystic fibrosis symptoms worse.

Children and adolescents:

When indicated for treating asthma:

Spiriva Respimat is intended for children age 6 years old and up; there is insufficient information about safety and efficacy in children under 6 years old.

When indicated for treating COPD:

This disease occurs in adults so use in children is not applicable.

Other medicines and Spiriva Respimat:

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your physician or pharmacist. Particularly if you are taking, or if you have taken, other anticholinergic medicines such as ipratropium or oxitropium.

No drug interaction side effects have been reported when Spiriva Respimat was taken with other products used to treat COPD or asthma such as breathlessness reliever inhalers (such as salbutamol), methylxanthines (such as theophylline), antihistamines, mucolytics, leukotriene antagonists (such as montelukast), cromones, anti-IgE (such as omalizumab), and/or inhaled or oral steroids (such as budesonide, prednisolone).

Pregnancy, breastfeeding, and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before taking this medicine. Do not use this medicine unless specifically recommended by your physician.

Driving and using machines:

No studies on the effects of this medicine on the ability to drive and use machines have been performed. If you experience dizziness or blurred vision, your ability to drive and use machinery may be affected.

Important information about some of this medicine's ingredients

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.

3. How to use this medicine?

Always use this medicine according to your physician's instructions. Check with your physician or pharmacist if you are not sure.

Spiriva Respimat is given by inhalation only. Only your physician will determine your dose and how you should take this medicine.

The recommended dose indicated for treating asthma in children 6 years old and up and in adults is usually:

Use Spiriva Respimat **ONCE A DAY**. Take two puffs every time you use it, if possible at the same time of day (because Spiriva Respimat is effective for 24 hours).

The recommended dose indicated for COPD in adults:

Use Spiriva Respimat **ONCE A DAY**. Take two puffs every time you use it, if possible at the same time of day (because Spiriva Respimat is effective for 24 hours).

As COPD and asthma are long-term diseases you must use Spiriva Respimat every day and

not only when you experience breathing problems.

Do not exceed the recommended dose.

Make sure that you understand how to use your Spiriva Respimat inhaler. The instructions for using the Spiriva Respimat inhaler are provided below.

If you have accidentally taken a higher dose

If you take more than two puffs in one day, consult your physician immediately. You may experience side effects such as dry mouth, constipation, difficulty passing urine, increased heart rate, or blurred vision.

If you have taken an overdose, or if a child has accidentally inhaled some medicine, immediately see a physician or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine

If you forget to take your daily dose (two puffs once a day), take it 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.

Adhere to the treatment as recommended by your physician. Even if your health improves, do not stop taking this medicine without consulting your physician.

If you stop taking this medicine

Before you stop using Spiriva Respimat, talk to your physician or your pharmacist. If you stop taking Spiriva Respimat too soon the symptoms of COPD and asthma may worsen.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, ask your physician or pharmacist.

4. Side effects

Like with all medicines, using Spiriva Respimat may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your physician immediately in case of:

- Immediate allergic reactions such as rash, nettle rash (urticaria), swelling of the mouth and face or sudden difficulties in breathing or other hypersensitivity reactions (such as sudden reduction of your blood pressure or dizziness) which may occur individually or as part of a severe allergic reaction (anaphylactic reaction) after administration of Spiriva Respimat.
- In addition, in common with all inhaled medicines, some patients may experience an unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhaling Spiriva Respimat (bronchospasm).

The following possible side effects have been reported by users of this medicine. They are listed in order of frequency:

For COPD:

Common side effects (affect 1-10 in 100 users):

- dry mouth

Uncommon side effects (affect 1-10 in 1,000 users):

- dizziness
- headache
- cough
- inflammation of the throat (pharyngitis)
- hoarseness
- constipation
- fungal infections of the oral cavity and throat
- rash
- itching
- difficulty passing urine (urinary retention)
- painful urination

Rare side effects (affect 1-10 in 10,000 users):

- insomnia
- irregular heartbeat (atrial fibrillation, supraventricular tachycardia)
- strong heartbeat (palpitations)
- faster heartbeat (tachycardia)
- nosebleed
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- difficulty swallowing
- seeing halos around lights or colored images in association with red eyes (glaucoma)
- increased pressure in the eye
- blurred vision
- inflammation of the larynx (laryngitis)
- heartburn

- dental caries
- inflammation of the gums
- inflammation of the tongue
- severe allergic reaction that causes swelling of the mouth and face, or throat
- nettle rash (urticaria)
- infections or ulcerations of the skin
- dryness of the skin
- urinary tract infection

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- inflammation of the mouth
- hypersensitivity (allergy), including immediate allergic reactions
- dehydration
- inflammation of the sinuses (sinusitis)
- blockage of intestines or absence of bowel movements (including paralytic ileus)
- nausea
- severe allergic reaction (anaphylactic reaction)
- swelling of joints

For asthma:

Uncommon side effects (affect 1-10 in 1,000 users):

- dry mouth
- dizziness
- headache
- difficulty in sleeping (insomnia)
- strong heartbeat (palpitations)
- cough
- inflammation of the throat (pharyngitis)
- hoarseness
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- fungal infections of the oral cavity and throat

- rash

Rare side effects (affect 1-10 in 10,000 users):

- nosebleed
- constipation
- itching
- inflammation of the gums
- inflammation of the mouth
- severe allergic reaction that causes swelling of the mouth and face, or throat
- nettle rash (urticaria)
- hypersensitivity (allergy), including immediate allergic reactions
- urinary tract infections

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- irregular heartbeat (atrial fibrillation, supraventricular tachycardia)
- faster heartbeat (tachycardia)
- difficulty swallowing
- difficulty passing urine (urinary retention)
- painful urination
- seeing halos around lights or colored images in association with red eyes (glaucoma)
- increased pressure in the eye
- blurred vision
- inflammation of the larynx (laryngitis)
- heartburn
- dental caries
- inflammation of the tongue
- infections or ulcerations of the skin
- dryness of the skin
- dehydration
- inflammation of the sinuses (sinusitis)
- blockage of intestines or absence of bowel movements (including paralytic ileus)

- nausea
- severe allergic reaction (anaphylactic reaction)
- swelling of joints

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your physician.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects:

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use the medicine after the expiry date (exp. date) which is stated on the carton and label. The expiry date refers to the last day of that month.
- Do not use Spiriva Respimat for longer than **three months after first use** (see instructions for use below).
- Store below 25°C. Do not freeze.
- Do not discard medicines in the garbage or in the sink. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

The active ingredient is tiotropium. 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 to the patient by inhalation after it has passed the mouthpiece.

- In addition to the active ingredient, this medicine also contains:

benzalkonium chloride, disodium edetate, purified water and hydrochloric acid 3.6 % for pH adjustment.

- What the medicine looks like and contents of the pack: The Spiriva Respimat pack contains one cartridge with inhalation solution and one Respimat inhaler. The cartridge must be connected to the inhaler before the first use.

The cartridge provides 60 puffs (30 medicinal doses).

- Registration holder: Boehringer Ingelheim Israel Ltd., 89 Medinat Hayehudim St., POB 4124, Herzlia Pituah 4676672.
- Manufacturer: Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany.

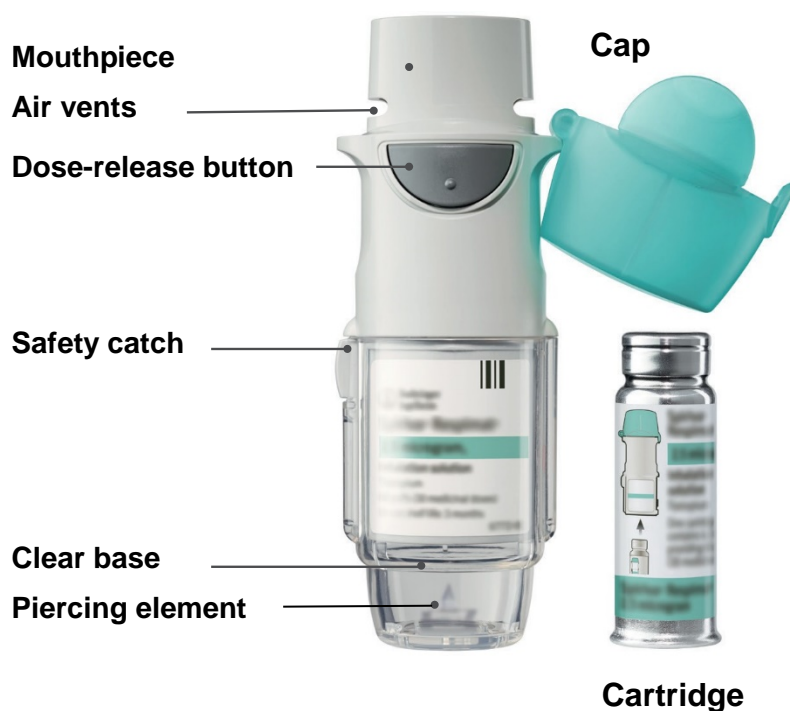
- This leaflet was reviewed and approved by the Ministry of Health in: July 2019.
- Registration number of the medicine in the Ministry of Health's National Drug Registry: 154-11-34255-00

Instructions for use

Introduction

Read these Instructions for Use before you start using Spiriva Respimat (tiotropium bromide). Use this inhaler only **ONCE A DAY**. Each time you use it take **TWO PUFFS**.

Children must use Spiriva Respimat with an adult's assistance.



- If you have not used Spiriva Respimat for more than 7 days, start by releasing one puff toward the ground.
- If you have not used Spiriva Respimat 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 inhaler

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 the performance of your Spiriva Respimat. If necessary, wipe the outside of your Spiriva Respimat inhaler with a damp cloth.



Prepare Spiriva Respimat for first use:

1. Removing the clear base

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



2. Inserting the cartridge

- Insert the narrow end of the cartridge into the inhaler. in the direction shown in the picture.
- Place the inhaler on a firm surface and push down until the cartridge clicks into place.



3. Putting the clear base back on

- Push 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 you hear a click (half a turn).



5. OPEN

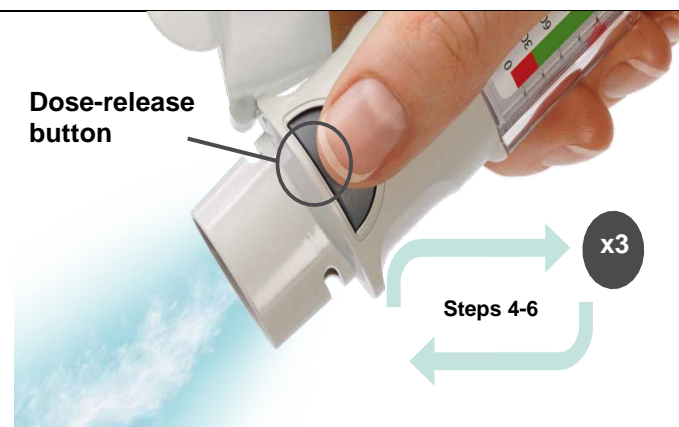
- OPEN the cap until it snaps fully open.



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 you hear a click (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** a second time so that you inhale a total of two puffs.

