Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986
This medicine is to be supplied by physician's prescription only

SPIRIVA®

Inhalation powder, hard capsules

Each Spiriva capsule contains 18 mcg Tiotropium (as bromide monohydrate).
Each Spiriva capsule also contains 5.5 mg lactose monohydrate.

Inactive ingredients and allergens in the medicine - See section 6.

Read the entire leaflet carefully before using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the 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.

This medicine is not intended for children and adolescents under the age of 18.

1. What is this medicine intended for?

Spiriva is indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) (a lung disease that causes shortness of breath and coughing).

Therapeutic group: Anticholinergics.

More about the medicine
Spiriva helps patients with COPD to breathe more easily. COPD is a chronic lung disease causing shortness of breath and coughing. The medical condition of COPD is associated with chronic inflammatory states of the airways (bronchitis) and emphysema. Since COPD is a chronic disease, you should take Spiriva every day, and not only when you experience breathing problems or other COPD symptoms.

Spiriva is a long acting bronchodilator assisting in the opening of airways, thus making it easier to get air in and out of the lungs. Regular use of Spiriva may help you when you suffer from shortness of breath resulting from your disease, and may also help to minimize the effects of the disease on your everyday life. Regular use of Spiriva will also help you to be more active. Daily use of Spiriva will also help to prevent sudden and short term worsening of COPD symptoms, which may last for several days. The medicine is active for more than 24 hours; therefore it should be taken only once a day. For dosage, see section 3. The manner of use and instructions for use are detailed in the end of this leaflet.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) or have previously experienced severe sensitivity (allergy) to the active ingredient tiotropium or to any of the other ingredients that this medicine contains (for the list of inactive ingredients, see section 6 - Additional Information).
- You are sensitive (allergic) to atropine or to similar medicines such as ipratropium or oxitropium, or if you are sensitive to lactose monohydrate which contains milk protein.

Special warnings regarding the use of this medicine

Before the treatment with Spiriva tell your physician if:

- Tell your physician if you have suffered a myocardial infarction during the last 6 months or experienced unstable or life threatening irregular heart rate or severe heart failure during the last year. This information is important in order to decide whether Spiriva is the right medicine for you.
- You suffer from narrow angle glaucoma, prostate problems or difficulty urinating.
- You suffer from kidney problems.

This medicine is indicated for maintenance treatment of chronic obstructive pulmonary disease. It should not be used to treat a sudden attack of breathlessness or wheezing.
Please consult your physician immediately if the following allergic reactions occur immediately after administration of Spiriva: skin rash, swelling, itching, wheezing or shortness of breath.
Inhaled medicines such as Spiriva may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation. If this occurs, consult your physician immediately.
When you take Spiriva, take care not to let any of the powder enter your eyes as this may result in precipitation or worsening of an eye disease called narrow-angle glaucoma.

If any powder does get into your eyes and you experience discomfort, blurred vision or eye pain, or if you see halos around lights or colored images in association with red eyes - these might be signs of an acute attack of narrow-angle glaucoma. Eye symptoms may be accompanied by headache, nausea or vomiting. You should stop using Spiriva and immediately consult a physician, preferably an eye specialist, when signs and symptoms of narrow-angle glaucoma appear.
Dry mouth, which may occur with anticholinergic treatment (medicines belonging to the group of tiotropium bromide), may in the long term be associated with dental caries. Therefore, remember to pay attention to oral hygiene.
This medicine should not be used more than once daily.

If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements, inform your physician or pharmacist. In particular inform the physician or the pharmacist if you are taking or have previously taken similar medicines for your lung disease, such as ipratropium or oxitropium.

No specific side effects were reported upon taking Spiriva in combination with other drugs for the treatment of COPD, such as inhalers for relief of shortness of breath, e.g. salbutamol, methylxanthines (such as theophylline) and/or oral or inhaled steroids, e.g. prednisolone.

Pregnancy and breastfeeding
If you are pregnant, think you may be pregnant, or breastfeeding, you should consult a physician before starting to take this medicine.
Do not use the medicine unless it has been explicitly recommended by the physician.

Driving and using machines
Use of this medicine may cause dizziness, blurred vision or headache and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery, and in any other activity which requires alertness.

Important information about some of the medicine's ingredients
Each Spiriva capsule contains 5.5 mg lactose monohydrate (milk sugar).
If you have been told by the physician that you are sensitive to certain sugars, contact the physician prior to using this medicine.

3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure. The dosage and treatment will be determined only by the physician. **Do not exceed the recommended dose.**

- The standard dosage is inhaling the content of one capsule (18 mcg of tiotropium) once a day.
- Try to take the medicine at the same time each day. Intake at the same time is important since Spiriva is effective for more than 24 hours.
- The capsules are intended only for inhalation using the Handihaler device. Do not swallow the capsules!
- The HandiHaler device, in which you should put the Spiriva capsule, makes holes in the capsule and allows you to inhale in the powder.
- Place one Spiriva capsule in the center chamber of the HandiHaler and follow the Instructions for Use of the device. The Instructions for Use of the HandiHaler are detailed below.
- Make sure that you have a HandiHaler and that you can use it properly.
- Please avoid breathing into the mouthpiece of the HandiHaler at any time.
- If you experience difficulties using the HandiHaler, ask the physician, nurse or pharmacist to show you how to use the device.
- You should clean your HandiHaler once a month. Cleaning instructions for the HandiHaler are detailed below.
- Avoid contact between the medicine powder and the eyes. If any powder does get into your eyes you may get blurred vision, eye pain and/or red eyes, you should wash your eyes in warm water immediately. Then refer to your physician immediately.
- If you feel that your respiratory condition has deteriorated, contact your physician as soon as possible.

If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally swallowed the medicine, contact the physician immediately or go to a hospital emergency room and bring the medicine package with you. If you have inhaled more than one Spiriva capsule per day, contact the physician immediately. You may experience side effects such as dry mouth, constipation, difficulty urinating, increased heart rate or blurred vision.

If you forget to take the medicine
Take the medicine once you remember and the next dose at the usual time.
If it is time to take the next dose, skip the forgotten dose and take the next dose at the usual time. Do not take a double dose on the same day to compensate for the forgotten dose

If you stop taking the medicine
Persist with the treatment as recommended by the physician.
Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the physician.
Do not discontinue treatment with the medicine without consulting the physician. If you stop taking the medicine, the signs and symptoms of the disease may worsen.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them. If you have any further questions regarding the use of this medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, Spiriva may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Effects that require special attention

Serious side effects include allergic reaction which causes swelling of the face or throat (angioedema) or other hypersensitivity reactions (such as sudden drop in blood pressure or dizziness), which may occur independently or as part of a severe allergic reaction (anaphylactoid reaction) after taking Spiriva. In addition, similarly to any other inhaled medicine, some of the patients may experience unexpected tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm). If this occurs, consult your physician immediately.

The frequency of possible side effects detailed below is defined as follows:
Common: may affect 1 out of 10 users.
Uncommon: may affect 1 out of 100 users.
Rare: may affect 1 out of 1000 users.
Unknown frequency: The frequency cannot be evaluated based on the available information.

The side effects detailed below have been reported by patients taking the medicine and are listed in the order of frequency.

Common:

Mouth dryness: usually mild.

Uncommon:

- Dizziness
- Headache
- Taste disorders
- Blurred vision
- Irregular heartbeat
- Inflammation of the throat
- Hoarseness
- Cough
- Heart burn
- Constipation
- Fungal infections of the oral cavity and throat
- Rash
- Difficulties passing urine
- Painful urination

Rare:

- Difficulty in sleeping
- Seeing halos around lights or colored images in association with red eyes
- Increase in intraocular pressure
- Irregular heart rate
- Unusual rapid heart rate (tachycardia)
- Strong heartbeats (palpitations)

- Tightness of the chest associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- Nosebleed
- Inflammation of the larynx
- Inflammation of the sinuses (sinusitis)
- Blockage of intestines or absence of bowel movements
- Inflammation of the gums
- Inflammation of the tongue
- Difficulties swallowing
- Inflammation of the mouth
- Feeling sick (nausea)
- Hypersensitivity, including immediate reactions
- Serious allergic reaction which causes swelling of the face or throat (angioedema)
- Urticaria (nettle rash, usually accompanied by itching)
- Itching
- Infections of the urinary tract.

Unknown frequency:

- Depletion of body water (dehydration)
- Dental caries
- Severe allergic reaction (anaphylactoid reaction)
- Infections or ulcerations of the skin
- Dryness of the skin
- Swelling of joints.

If any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by the online form in the following link:
http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il

5. How to store the medicine?

- Store the medicine at a temperature below 25˚C. Do not freeze. Avoid storage under conditions of direct sunlight or heat.
- Avoid poisoning! This medicine and any other medicine should be kept in a close place out of sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton and blister. The expiry date refers to the last day of that month.
- After first opening of the blister, use the opened blister within 9 days, one capsule per day.
- Do not use the medicine if the package is defective.
- Do not discard the medicine to the wastewater or household waste. Consult the pharmacist about how to dispose of the medicine. These measures will help in environmental protection.

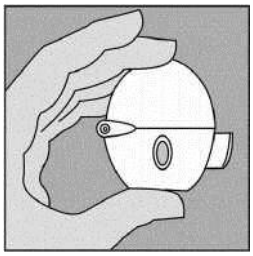
6. Additional information

Each capsule contains 18 mcg of the active ingredient Tiotropium (as bromide monohydrate). During inhalation, 10 mcg of Tiotropium are inhaled from the HandiHaler mouthpiece. The second ingredient is lactose monohydrate.
Capsule coating is composed of:
Polyethylene glycol, Titanium dioxide (E171), Yellow iron oxide (E172), Indigo carmine (E132), Gelatin, Ink.

- What does the medicine look like and what are the contents of the package:
  Spiriva is marketed as a carton box containing the HandiHaler device and foil coated blisters with hard opaque light green capsules, with the company logo and TI 01 code imprinted on the capsule.
  The package contains 30 capsules.
- Registration holder: Boehringer Ingelheim Israel Ltd., 89 Medinat Ha-Yehudim, P.O.B. 4124, Hertzliya-Pituach 4676672
- Manufacturer: Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rheine, Germany.
- This leaflet was checked and approved by the Ministry of Health in July 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 133-47-31120-00

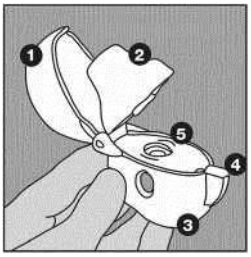
Instructions for Use

The following are the instructions for the patient on how to inhale from the Spiriva capsule by use of the HandiHaler device. The HandiHaler enables you to inhale the medicine contained in the Spiriva capsule that your physician has prescribed for your breathing problems.
Remember to carefully follow your physician's instructions for using Spiriva.
The HandiHaler is especially designed for Spiriva. You must not use it to take any other medication. You can use your HandiHaler for up to one year to take your medication.

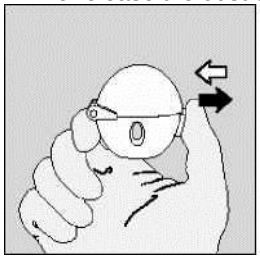


The HandiHaler is composed of:

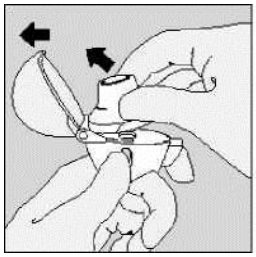
1. Top cover (dust cap)
2. Mouthpiece
3. Base
4. Piercing button
5. Center chamber



1. To release the dust cap press the piercing button completely in and release.


1

2. Open the dust cap completely by pulling it upwards. Then open the mouthpiece by pulling it upwards.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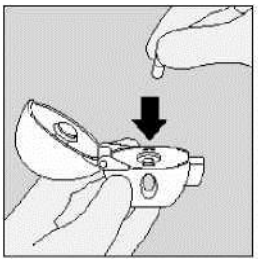
3. Remove a Spiriva capsule from the blister (only before use, see blister handling) and place it in the center chamber (5), as illustrated. It does not matter which way the capsule is placed in the chamber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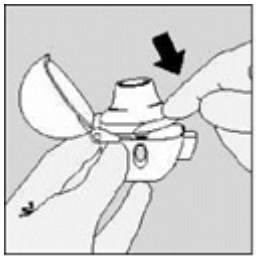
4. Close the mouthpiece firmly until you hear a click, leaving the dust cap open.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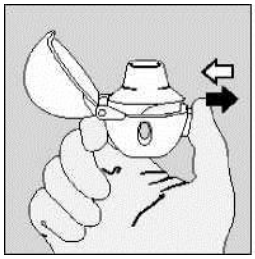
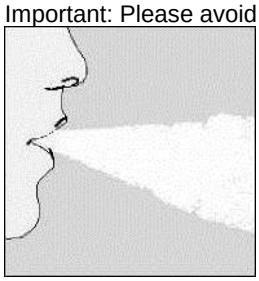
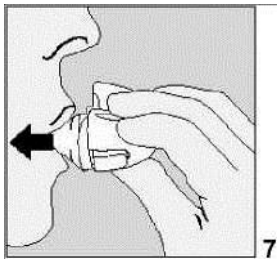
5. Hold the HandiHaler device with the mouthpiece upwards and press simultaneously the piercing button completely in, and release. This makes holes in the capsule and allows the medication to be released when you inhale.


5

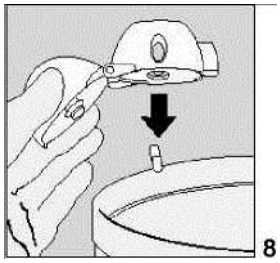
6. Breathe out completely.
   Important: Please avoid breathing into the mouthpiece at any time.



7. Raise the HandiHaler device to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position and breathe in slowly and deeply but at a rate sufficient to hear or feel the capsule vibrate. Breathe in until your lungs are full; then hold your breath as long as comfortable and at the same time take the HandiHaler out of your mouth. Resume normal breathing. Repeat steps 6 and 7 once again, in order to empty the capsule completely.

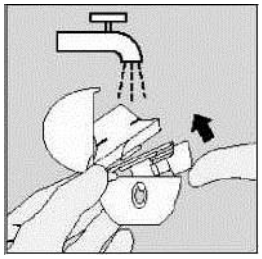

7

8. Open the mouthpiece again. Tip out the used capsule and dispose. Close the mouthpiece and dust cap for storage of your HandiHaler device.


8

Cleaning your HandiHaler device

Clean the HandiHaler once a month. Open the dust cap and mouthpiece. Then open the base by lifting the piercing button. Rinse the complete inhaler with warm water to remove any powder. Dry the HandiHaler thoroughly by tipping excess of water out on a paper towel and air dry afterwards, leaving the dust cap, mouthpiece and base open. It takes 24 hours to fully air dry, so clean it right after you used it and it will be ready for your next dose. If needed, the outside of the mouthpiece may be cleaned with a moist but not wet tissue.



Blister handling

A. Separate the blister strips by tearing along the perforation.
B. Peel back foil (only immediately before use) using the tab until one capsule is fully visible.
   In case a second capsule is exposed to air inadvertently this capsule has to be discarded.
C. Remove capsule.
   Spiriva capsules contain a small amount of powder so that the capsule is only partially filled.