

SPIRIVA[®] INHALATION POWDER, HARD CAPSULE

Consumer Medication Information Leaflet (RiMUP)

Tiotropium (18 microgram)

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What SPIRIVA is used for

SPIRIVA helps people who have narrowing of airway and breathing difficulty associated chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath and coughing. The term COPD is associated with the inflammation of the mucous membrane in the bronchial tubes and the condition in which the air sacs of the lungs are damaged and enlarged, causing breathlessness. As COPD is a chronic disease you should take SPIRIVA every day for long term and not only when you have breathing problems or other symptoms of COPD.

How SPIRIVA works

SPIRIVA 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 can also help you when you have on-going shortness of breath related to your disease and will help you to minimise the effects of the disease on your everyday life. It also helps you to be active longer. Daily use of SPIRIVA will also help to prevent sudden, short-term worsening of your COPD symptoms which may last for several days.

The effect of this medicine lasts for 24 hours, so you only need to take it once a day. For correct dosing of SPIRIVA please see section How to use SPIRIVA

and the instructions for use provided on the other side of the leaflet.

Before you use SPIRIVA

- When you must not use it

You should not use SPIRIVA if you are allergic (hypersensitive) to tiotropium or to lactose monohydrate which contains milk protein.

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

You should not use SPIRIVA on infants or children.

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

You should not use SPIRIVA for initial treatment of acute episodes of bronchospasm, i.e. rescue therapy.

Do not take Spiriva 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, talk to your doctor or pharmacist if you:

- are suffering from increased eye pressure, 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 specific side effects have been reported when SPIRIVA has been taken together with other products used to treat COPD such as reliever inhalers e.g. salbutamol, methylxanthines e.g.

theophylline and/or oral and inhaled steroids e.g. prednisolone.

How to use SPIRIVA

Do not swallow the capsules.

The HandiHaler device, which you should put the SPIRIVA capsule into, makes holes in the capsule and allows you to breathe in the powder.

Make sure that you have a HandiHaler and that you can use it properly. The instructions for use of the HandiHaler are provided on the other side of this leaflet.

Make sure that you do not blow into the HandiHaler.

If you have any problems using the HandiHaler, ask your doctor, nurse or pharmacist to show you how it works

- How much to use

The recommended dose is to inhale the contents of 1 capsule (18 micrograms of tiotropium) once a day. Do not take more than the recommended dose.

Once you have taken your first capsule from the blister strip you must continue to take the capsules for the next 9 days, one capsule a day, from the same strip.

- When to use it

You should try to take the capsule at the same time every day. This is important because SPIRIVA is effective over 24 hours.

- How long to use it

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

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

- If you forget to use it

If you forget to take a 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 inhale from more than 1 capsule of SPIRIVA in a day, you should talk to your doctor immediately. You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, increased heartbeat, blurred vision or pink eye.

While you are using SPIRIVA

- 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.

You should clean your HandiHaler once a month. Cleaning instructions for the HandiHaler are provided on the other side of this leaflet.

- Things you must not do

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Spiriva to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

When taking SPIRIVA, take care not to let any of the powder enter your 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 talk to your doctor immediately for further information.

If you feel that your breathing is worsening, you should tell your doctor as soon as possible.

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 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 (insomnia)

Eye disorders:
vision blurred
pressure within the eye increased (intraocular pressure increased)
seeing halos around lights or coloured images in association with red eyes (glaucoma)

Cardiac disorders:
faster heart beat (tachycardia)
feeling your heartbeat (palpitations)
irregular heart beat (supraventricular tachycardia)
irregular heart beat (atrial fibrillation)

Respiratory, thoracic and mediastinal disorders:
nosebleed (epistaxis)
inflammation of the larynx/voice box (laryngitis)
inflammation of the throat (pharyngitis)
inflammation of the sinuses (sinusitis)
speech disturbance resulting in a hoarse voice (dysphonia)
cough

Gastro-intestinal disorders:
blockage of intestines or absence of bowel movements (intestinal obstruction including ileus paralytic)
inflammation of the mouth (stomatitis)
inflammation of the gums (gingivitis)
inflammation of the tongue (glossitis)
fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
heart burn (gastrooesophageal reflux disease)
difficulties swallowing (dysphagia)
constipation
dry mouth, usually mild

Skin and subcutaneous tissue disorders,

Immune system disorders:
hypersensitivity (including immediate reactions)
skin infection and skin ulcer
nettle rash (urticarial)
itching (pruritus)
dry skin
rash

Musculoskeletal and connective tissue disorders:
joint swelling

Renal and urinary disorders:
urinary retention (usually in men with predisposing factors)
urinary tract infection
painful urination (dysuria)

Serious side effects include allergic reactions which cause swelling of the face or throat (angioedema) or tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm). If this occurs, please consult your doctor immediately.

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

- Storage

Keep out of the reach and sight of children
After first opening of the blister, use within 9 days
Store below 25°C.
Do not freeze.

- Disposal

Do not use SPIRIVA 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.

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, inhalation powder, light green hard capsules containing white or

yellowish white powder with the product code TI 01 and company logo printed on the capsule.

The product is available in the following packs:

A pack containing 30 capsules

A pack containing 10 capsules and 1 HandiHaler.

- Ingredients

- Active ingredient:

tiotropium 18 mcg

equivalent to 22.5 mcg tiotropium

bromide monohydrate (INN = tiotropium bromide)

-Inactive ingredients:

lactose monohydrate (which contains milk protein)

- MAL number

MAL20032406AZ

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG

Binger Strasse 173

55216 Ingelheim am Rhein

Germany

for

Boehringer Ingelheim International

GmbH

Ingelheim am Rhein

Product Registration Holder

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Bhd.

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Date of revision

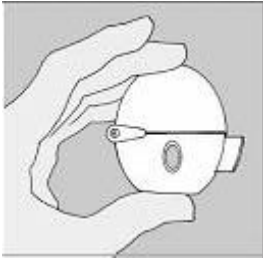
15/06/2017

Serial Number

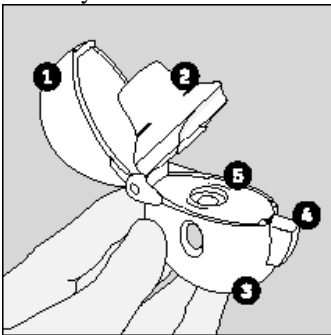
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INSTRUCTIONS FOR USE
Spiriva Inhalation Powder, Hard
Capsule.

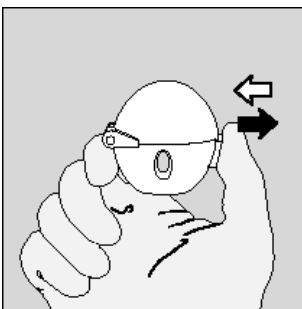
Remember to carefully follow your doctor's instructions for using SPIRIVA.



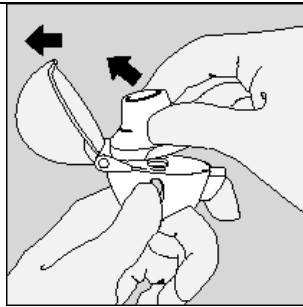
The HandiHaler® is an inhalation device especially designed for inhalation from SPIRIVA capsules. You must not use it to take any other medication. You can use your HandiHaler® for up to one year to take your medication.



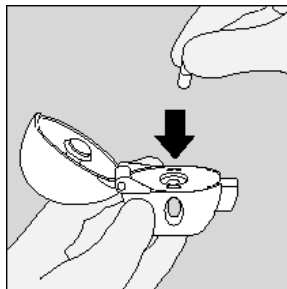
1. dust cap
2. mouthpiece
3. base
4. piercing button
5. centre chamber



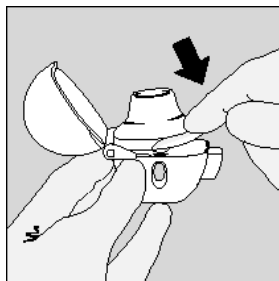
1. To release the dust cap press the piercing button completely in and let go.



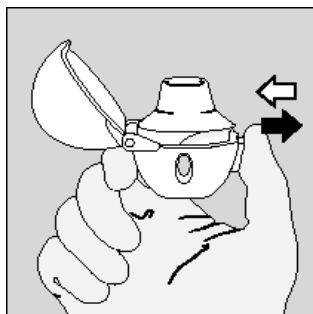
2. Open the dust cap completely by pulling it upwards. Then open the mouthpiece by pulling it upwards.



3. Remove a SPIRIVA capsule from the blister (only immediately before use, see blister handling) and place it in the centre chamber (5), as illustrated. It does not matter which way the capsule is placed in the chamber.

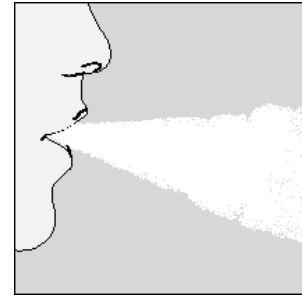


4. Close the mouthpiece firmly until you hear a click, leaving the dust cap open.

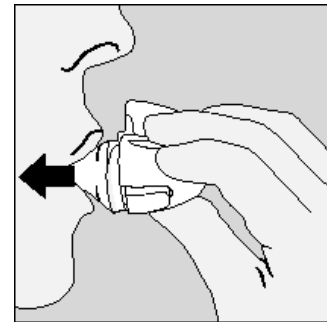


5. Hold the HandiHaler® device with the mouthpiece upwards and press the piercing button completely in only once, and release. This makes holes in the

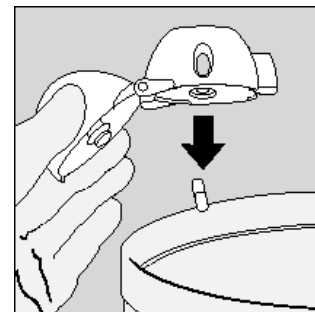
capsule and allows the medication to be released when you breathe in.



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

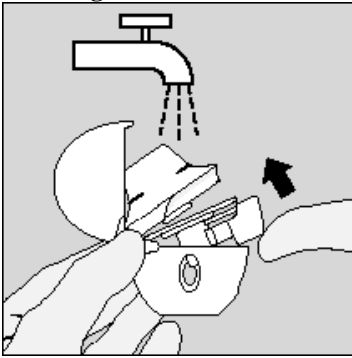


7. Raise the HandiHaler® to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position and breathe in slowly and deeply but at a rate sufficient to hear or feel the capsule vibrate. Breathe in until your lungs are full; then hold your breath as long as comfortable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

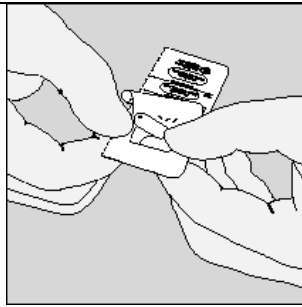


8. Open the mouthpiece again. Tip out the used capsule and dispose. Close the mouthpiece and dust cap for storage of your HandiHaler® device.

Cleaning the HandiHaler

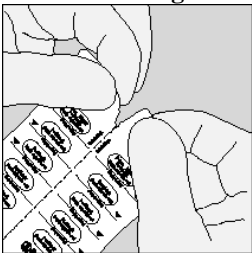


Clean the HandiHaler® once a month. Open the dust cap and mouthpiece. Then open the base by lifting the piercing button. Rinse the complete inhaler with warm water to remove any powder. Dry the HandiHaler® thoroughly by tipping excess water out onto a paper towel and air-dry afterwards, leaving the dust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

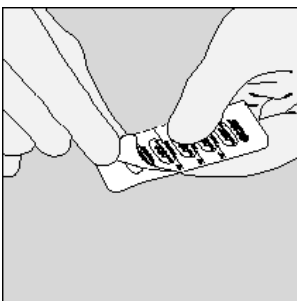


C. Remove capsule. The capsules should not be exposed to extreme temperatures. SPIRIVA capsules contain only a small amount of powder so that the capsule is only partially filled.

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.