If you have any problems using the HandiHaler, ask your doctor, nurse or pharmacist to show you how it works. You should clean your HandiHaler once a month. Cleaning instructions for the HandiHaler are provided on the other side of this leaflet.

When taking Spiriva microgram, take care not to let any of the powder enter your eyes. If any powder does get into your eyes, you may be blinded, vision, eye pain and/or red eyes, you should wash your eyes in warm water immediately. Then talk to your doctor immediately for further advice.

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

If you take more Spiriva microgram than you should If you inhale from more than 1 capsule of Spiriva microgram in a day, you should consult your doctor immediately. You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, irritability, blurred vision, or headache. If you forget to take Spiriva microgram 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 stop taking Spiriva microgram Before you stop taking Spiriva microgram, you should talk to your doctor. Please note, do not stop taking Spiriva microgram the signs and symptoms of COPD may worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Evaluation of the side effects is based on the following frequencies:

- Common: may affect up to 1 in 10 people
- Uncommon: may affect up to 1 in 100 people
- Rare: may affect up to 1 in 1,000 people
- Not known: frequency cannot be estimated from the available data

The side effects described below have been experienced by people taking this medicine and they are listed according to frequency as common, uncommon, rare or not known.

Common:
- Dry mouth: this is usually mild and temporary
- Dizziness
- Headache
- Nasal catarrh
- Blurred vision
-Irregular heart beat (atrial fibrillation)
- Sore throat
- Hoarseness (dysphonia)
- Dry mouth
- Heart burn (gastroesophageal reflux disease)
- Constipation
- Fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- Rash
- Difficulty passing urine (urinary retention)
- Painful urination (dysuria)

Rare:
- Difficulty in sleeping (insomnia)
- Seeing halos around lights or coloured images in association with red eyes
- Increased of the measured eye pressure
- Irregular heart beat (sustained tachycardia)
- Faster heart beat (tachycardia)
- Feeling your heartbeat (palpitations)
- Tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- Nasal dryness
- Infarction of the larynx (laryngitis)
- Swelling of the gums (gingivitis)

- Inflammation of the tongue (glossitis)
- Difficulties swallowing (dysphagia)
- Inflammation of the mouth ( stomatitis)
- Feeling sick (nausea)
- Allergic reactions (hypersensitivity), including immediate reactions
- Severe allergic reaction (anaphylactic reaction)
- Swelling of the lips, tongue or throat
- Inflamed or tender portions of the skin
- Dryness of the skin
- Swelling of joints

Serious side effects include allergic reactions which cause swelling of the face or throat (or angioedema), which is a disease of the eyes. Eye symptoms may be accompanied by facial swelling, which can be severe.

Nasal dryness

The capsules are only for inhalation and not for oral intake. Do not swallow the capsules.

The HandiHaler device, which you should put the Spiriva capsule into, makes a clicking sound when you 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.

Please read the following questions carefully. If you can answer any of these questions with "yes" please discuss this with your doctor before taking Spiriva microgram.

• are you allergic to tiotropium, atropine or similar drugs such as ipratropium or oxtropium?
• are you taking any other medicinal products containing ipratropium or tiotropium?
• are you pregnant, do you think you are pregnant, or are you breast-feeding?
• are you suffering from narrow angle glaucoma, prostate problems or have difficulty passing urine?
• do you have any kidney problems?
• have you suffered from a myoccardial infarction during the last 6 months or from any unstable or life threatening irregular heart beat or severe heart failure within the past year?
• Do not take Spiriva microgram

You should not use Spiriva microgram if you are allergic (hypersensitive) to tiotropium, its active ingredient or to lactose monohydrate which contains milk protein.

You should also not use Spiriva microgram if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxtropium.

Precautions and warnings

Talk to your doctor if you suffer from narrow angle glaucoma, prostate problems or have difficulty passing urine.

If you have problems with your kidneys, please consult your doctor.

• SPIRIVA 18 microgram is indicated for maintenance treatment of your chronic obstructive pulmonary disease, it should not be used to treat a sudden attack of breathlessness or wheezing.
• Immediate allergic reactions which cause swelling of the face, rash, swelling, itching, wheezing or breathlessness may occur after administration of SPIRIVA 18 microgram. If this occurs, please consult your doctor immediately.
• Inhaled medicines such as SPIRIVA 18 microgram may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation, please consult your doctor immediately.
• Take care not to let the inhalation powder enter your eye as this may result in precipitation or worsening of narrow-angle glaucoma, which is a disease of the eyes. Eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes may be signs of an acute attack of narrow-angle glaucoma. Eye symptoms may be accompanied by facial swelling, which can be severe.

Dryness of the skin

• SPIRIVA 18 microgram helps people who have 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 conditions chronic bronchitis and emphysema. As COPD is a chronic disease you should take SPIRIVA 18 microgram every day and not only when you have breathing problems or other symptoms of COPD.

SPIRIVA 18 microgram 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 18 microgram can 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 18 microgram will also help to improve your tolerance of exercise, short-term improvement 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 18 microgram see 3. Immediately after inhalation (bronchospasm).

The capsules are only for inhalation and not for oral intake.

3. How to take Spiriva microgram

Follow your doctor’s instructions about when and how to take your medicine. If you are unsure ask your doctor or pharmacist.

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.

Spiriva microgram is not recommended for children and adolescents under 18 years.

5. How to store Spiriva microgram

Keep out of the reach of and out of the sight of children. Do not store Spiriva microgram 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.

6. Contents of the pack and other information

What Spiriva micrograms contains

Each capsule contains 18 micrograms of the active ingredient tiotropium (as bromide monohydrate). During inhalation, 10 micrograms tiotropium are delivered from the capsule. (as bromide monohydrate). During inhalation, 10 micrograms tiotropium are delivered from the capsule.

What Spiriva microgram looks like and contains of the pack

Spiriva microgram, inhalation powder, hard capsule is a light green hard capsule with the product code TI 01 and company logo printed on the capsule.

The HandiHaler is a single dose inhalation device with a grey dust cap and a green pilfering button. The powder in the capsule is the following in the package size: A pack containing 30 capsules and 1 HandiHaler

Manufacturer

The manufacturer for Spirova 18 microgram and HandiHaler device is: Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Straße 193, D-55521 Ingelheim am Rhein, Germany. Phone: 06131/60. Product licence holder: Ecosse Pharmaceuticals Ltd., 3 Young Place, East Kilbride, G75 0TD. Repackaged by: Munro Wholesale Medical Supplies Ltd., 3 Young Place, East Kilbride, G75 0TD. PL 19065/0330 This leaflet was revised: 05.05.2015 E0330-5

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Dear Patient,
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 doctor’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®
1. Dust cap
2. Mouthpiece
3. Base
4. Piercing button
5. Centre chamber

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

Open the dust cap completely by pulling it upwards.

Then open the mouthpiece by pulling it upwards.

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.

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

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 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.

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

Cleaning your 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 of water out on 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 right after you have 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.

Remove capsule.
SPIRIVA capsules contain only a small amount of powder so that the capsule is only partially filled.

Manufacturer of the HandiHaler® device:
Boehringer Ingelheim Pharma GmbH & Co. KG
D-55216 Ingelheim am Rhein Germany

Blister handling
Separate the blister strips by tearing along the perforation.
In case a second capsule is exposed to air inadvertently this capsule has to be discarded.

Blister handling

Separate the blister strips by tearing along the perforation.

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.