Spiriva 18 microgram, inhalation powder, hard capsule

What is in this leaflet:
- Keep this leaflet. You may need to read it again.
- If you get any side effects, talk to your doctor or pharmacist. These may be symptoms of an allergic reaction.

Before you use Spiriva 18 microgram
- Please read this leaflet carefully before you start using this medicine. This leaflet contains information for you and your doctor. It is important that you understand your medicine and how to use it properly.
- If you have any questions, ask your doctor or pharmacist.

What is Spiriva 18 microgram?
Spiriva 18 microgram is a medicine used to treat chronic obstructive pulmonary disease (COPD) to breathe more easily. It is helpful for people who have had a chronic cough with phlegm and shortness of breath for at least 3 months each year over the past 2 years. It is also helpful in sudden, short-term worsening of your stable COPD. If you are allergic to atropine or substances with the same active ingredient as Spiriva 18 microgram, you should not use it.

How to use Spiriva 18 microgram
- You should take one capsule of Spiriva 18 microgram once a day at the same time each day. You should take it with a glass of water or milk. It is important not to exceed the recommended dose of 1 capsule a day.
- Before using Spiriva 18 microgram, make sure you are not allergic to any of the ingredients of the medicine.
- If you have been told by your doctor that you must continue to take the capsules for the next 9 days, one capsule each day, you should take it immediately after the blister is opened. If you do not, you will not get the full benefit of the medicine.

What is Spiriva 18 microgram used for?
Spiriva 18 microgram is used to treat chronic obstructive pulmonary disease (COPD) to breathe more easily. It is helpful for people who have had a chronic cough with phlegm and shortness of breath for at least 3 months each year over the past 2 years. It is also helpful in sudden, short-term worsening of your stable COPD.

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What to do if you forget to take a dose
- If you forget to take a dose, take one as soon as you remember. Do not take a double dose to make up for the missed dose.
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What to do if you take too much Spiriva 18 microgram
- If you take too much Spiriva 18 microgram, talk to your doctor or pharmacist immediately.
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Possible side effects
- Like all medicines, Spiriva 18 microgram can cause side effects, although not everyone gets them.
- The side effects described below have been experienced by patients taking this medicine and are listed according to frequency in either common, uncommon, rare or very rare.
- Common (may affect up to 1 in 10 people):
- Severe allergic reaction (anaphylactic reaction)
- Abdominal cramps
- Cough
- Inflammation of the gums (gingivitis)
- Inflammation of the larynx (laryngitis)
- Irregular heart beat (supraventricular tachycardia)

Uncommon (may affect up to 1 in 100 people):
- Fungal infections of the oral cavity and throat
- See section 4. Your doctor or pharmacist will be able to decide whether the benefits of Spiriva 18 microgram outweigh the possible side effects.

Very rare (may affect up to 1 in 10,000 people):
- An increased risk of infection
- A change in your blood cells

What if you get any side effects?
If you get any side effects, talk to your doctor or pharmacist. These may be symptoms of an allergic reaction.

How to store Spiriva 18 microgram
- Keep this medicine out of the sight and reach of children.
- Keep the bottle tightly closed.
- Do not use Spiriva 18 microgram after the expiry date which is stated on the blister and the bottle. The expiry date refers to the last day of that month.
- If you get any side effects, talk to your doctor or pharmacist.

Marketing Authorisation Holder and Manufacturer
The marketing authorization holder for Spiriva 18 microgram is Boehringer Ingelheim International GmbH, P.O. Box 173, 55216 Ingelheim am Rhein, Germany.

The manufacturer for Spiriva 18 microgram is Boehringer Ingelheim Pharma GmbH & Co. KG, P.O. Box 173, 55216 Ingelheim am Rhein, Germany.

This medicine is authorised in the member States of the European Economic Area and in the United Kingdom.

For other, non-EU countries, please check the relevant regulatory authorities.

Allowance
- Bulgaria
- Czech Republic
- Germany
- France
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovenia
- Spain
- Sweden
- Turkey

Packaging
- 300901-23
- Hard capsule
- 18 microgram
- BLACK
- 300901-23

Print colors:
- P007281
- 300901-23
- HARD CAPSULE

Material:
- A pack containing 60 capsules
- The other ingredient is lactose monohydrate 18 microgram of the active ingredient tiotropium bromide 18 microgram. If you have been told by your doctor that you must continue to take the capsules for the next 9 days, one capsule each day, you should take it immediately after the blister is opened. If you do not, you will not get the full benefit of the medicine.

Carefully read the leaflet before use. Ask your pharmacist for further information on the safe use of the medicine.

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

You should not use this medicine unless specifically recommended by your doctor.

You should clean your HandiHaler once a month. Cleaning the HandiHaler device 12 months after first use.

The manufacturer for Spiriva 18 microgram is:
Boehringer Ingelheim International GmbH, P.O. Box 173, 55216 Ingelheim am Rhein, Germany.
Instructions on how to use the HandiHaler device

The HandiHaler is an inhalation device that enables you to inhale the medicine contained in the Spiriva capsule – that your doctor has prescribed for your breathing problems. The HandiHaler is especially designed for Spiriva. You must not use it to take any other medicine. It is for you only and intended for multiple uses.

1. Remove a Spiriva capsule from the blister (only immediately before use, see blister handling) and place it in the centre chamber (1), as illustrated. It does not matter which way the capsule is placed in the chamber.

2. Peel back foil (only immediately before use) using the tab until one capsule is fully visible.

3. Separate the Spiriva blister strips by tearing along the perforation.

4. Hold the HandiHaler device with the mouthpiece upwards and press the piercing button (6) completely in and let go. This makes holes in the strip and allows the medicine to be released when you inhale.

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

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

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

8. 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 and hold your breath as long as comfortable. At the same time take the HandiHaler out of your mouth.

9. Resume normal breathing. Repeat steps 6 and 7 once, in order to empty the capsule completely.

Remember to carefully follow your doctor’s instructions for using Spiriva. After first use, you can use your HandiHaler for up to one year to take your medication.

Cleaning your HandiHaler

Clean the HandiHaler once a month. Open the dust cap and mouthpiece. Then open the base by lifting the piercing button. Then separate the complete strip with warm water to remove any powder. Dry the HandiHaler thoroughly by wiping excess of water away with a paper towel. If the HandiHaler is kept in a bathroom, cleaning the dust cap, mouthpiece and base open. It takes 24 hours to air dry, so store it immediately after use so that 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

Remove a Spiriva capsule from the blister (only immediately before use, see blister handling) and place it in the centre chamber (1), as illustrated. It does not matter which way the capsule is placed in the 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. Close the mouthpiece firmly until you hear a click, leaving the dust cap open.

4. Separate the Spiriva blister strips by tearing along the perforation.

5. Peel back foil (only immediately before use) using the tab until one capsule is fully visible.

6. In case a second capsule is exposed to air inadvertently this capsule has to be discarded.

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

The HandiHaler

Dust cap  MOUTHPIECE  Base  Piercing button  Centre chamber