1. What SPIRIVA 18 microgram is and what it is used for

SPIRIVA 18 microgram is an inhaled powder for use in the HandiHaler device. It contains tiotropium in the inhalation powder. Tiotropium is a medication used to treat chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath in people who have conditions related to it, such as chronic bronchitis and emphysema. As COPD is a chronic disease, SPIRIVA 18 microgram is effective in the long-term management of COPD.

Please read all of this leaflet carefully before you start using SPIRIVA 18 microgram. It will help you to get the most benefit from the drug.

If you have any problems using the HandiHaler, ask your pharmacist or doctor for help.

Before you start using SPIRIVA 18 microgram, read the information on the HandiHaler device, that comes with it.

2. How to use SPIRIVA 18 microgram

SPIRIVA 18 microgram is an inhaled powder for use in the HandiHaler device. It contains tiotropium in the inhalation powder. Tiotropium is a medication used to treat chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath in people who have conditions related to it, such as chronic bronchitis and emphysema. As COPD is a chronic disease, SPIRIVA 18 microgram is effective in the long-term management of COPD.

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3. How to use SPIRIVA 18 microgram

SPIRIVA 18 microgram is an inhaled powder for use in the HandiHaler device. It contains tiotropium in the inhalation powder. Tiotropium is a medication used to treat chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath in people who have conditions related to it, such as chronic bronchitis and emphysema. As COPD is a chronic disease, SPIRIVA 18 microgram is effective in the long-term management of COPD.

Please read all of this leaflet carefully before you start using SPIRIVA 18 microgram. It will help you to get the most benefit from the drug.

If you have any problems using the HandiHaler, ask your pharmacist or doctor for help.

Before you start using SPIRIVA 18 microgram, read the information on the HandiHaler device, that comes with it.

4. Possible side effects

Allergic reactions (hypersensitivity), including immediate reactions and delayed reactions

Infections of the urinary tract

- Itching (pruritus)
- Severe allergic reaction (anaphylactic reaction)
- Tooth decay (dental caries)

Uncommon (may affect up to 1 in 10 people):

- Cough
- Hoarseness (dysphonia)
- Blurred vision
- Taste disorders
- Headache

Rare (may affect up to 1 in 1,000 people):

- Difficulty passing urine (urinary retention)
- Rash

Very rare (may affect less than 1 in 1,000 people):

- Severe allergic reaction (anaphylactic reaction)
- Tooth decay (dental caries)
- Tooth loss

If you experience any side effects, speak to your doctor or pharmacist immediately.

5. How to store SPIRIVA 18 microgram

Keep this medicine out of the sight and reach of children. Do not throw away any medicines via wastewater or in the toilet. Do not freeze SPIRIVA 18 microgram. The original pack and all unused parts of the product must be disposed of in an environmentally friendly way.

For the original pack and all unused parts of the product, follow these steps:

- Keep the original pack and all unused parts of the product.
- Follow the instructions on the pack to dispose of the product in an environmentally friendly way.
- Do not throw away any medicines via wastewater or in the toilet.
- Do not freeze SPIRIVA 18 microgram.

6. Further information

If you have any questions, ask your doctor or pharmacist.

If you have any problems using the HandiHaler, ask your pharmacist or doctor for help.

Before you stop using SPIRIVA 18 microgram, you should talk to your doctor or pharmacist.

Marketing Authorization Holder and Manufacturer

The marketing authority holder for SPIRIVA 18 microgram is Boehringer Ingelheim GmbH & Co. KG. The manufacturer for SPIRIVA 18 microgram and the HandiHaler device is Boehringer Ingelheim Pharma GmbH & Co. KG.

Copyrigths

This medicinal product is authorised for marketing in the European Union and other countries where a marketing authorization has been issued.


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Spiriva 18 microgram, inhalation powder, hard capsule

Package leaflet: Information for the user

18 microgram, inhalation powder, hard capsule

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Information for the user

18 microgram, inhalation powder, hard capsule
1. What Spiriva 18 microgram is and what it is used for

Spiriva 18 microgram (tiotropium bromide) is a prescription inhalation powder that treats conditions that cause shortness of breath and cough. It is used for the long-term management of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. COPD is a disease of the lungs that makes it difficult to breathe.

2. How to use Spiriva 18 microgram

Spiriva 18 microgram is available as HandiHaler device. The capsules are only for inhalation and not for oral intake. You should try to use the capsule at the same time every day. The recommended dose is to inhale the contents of 1 capsule once daily. For correct dosing of SPIRIVA 18 microgram, consult the patient information leaflet provided with the device.

3. How to store Spiriva 18 microgram

Keep this medicine out of the sight and reach of children. Once you have taken your first capsule from the blister you must continue to take the capsules for the next 9 days, one capsule a day, from the same blister. Store the capsule at room temperature. Do not freeze.

4. Possible side effects

Common (may affect more than 1 in 10 people):
- Dryness of the skin
- Depletion of body water (dehydration)
- Inflammation of the sinuses (sinusitis)
- Inflammation of the gums (gingivitis)
- Inflammation of the mouth (stomatitis)
- Inflammation of the larynx (laryngitis)
- Fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- Blurred vision
- Difficulty in sleeping (insomnia)
- Painful urination (dysuria)
- Faster heart beat (tachycardia)
- Seeing halos around lights or coloured images in the field of vision
- Numbness or tingling of fingers, hands, toes, or feet

Uncommon (may affect up to 1 in 100 people):
- Headache
- Nose or throat infections
- Minor skin rash
- Wrist or ankle swelling
- Unusual tiredness
- Arthritis
- Osteoporosis

Rare (may affect up to 1 in 10,000 people):
- Painful heart palpitations
- Prolonged (long lasting) nausea
- Difficulty swallowing
- Dry mouth
- Hypersensitivity reactions (such as sudden reduction of your blood pressure)
- Dehydration
- Established age-related bone loss
- Tension (tensing up)
- Neutropenia

Very rare (may affect up to 1 in 100,000 people):
- Anaphylaxis (severe allergic reaction)
- Increased sweating
- Severe alteration of liver function

5. How to use Spiriva 18 microgram

Keep this medicine out of the sight and reach of children. Once you have taken your first capsule from the blister you must continue to take the capsules for the next 9 days, one capsule a day, from the same blister. Store the capsule at room temperature. Do not freeze.

6. Contents of the pack and other information

Spiriva 18 microgram is available as HandiHaler device. The capsules are only for inhalation and not for oral intake. This medicine is supplied in a blister pack containing 10 capsules and 1 HandiHaler device. If you get any side effects, talk to your doctor or pharmacist. The active substance in Spiriva 18 microgram is tiotropium bromide. The recommended dose is to inhale the contents of 1 capsule once daily.
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 medicine. You can use your HandiHaler for up to one year to take your medicine.

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

Separate the blister strips by tearing along the perforation.

Blister handling

1. Peel back foil (only immediately before use) using the tab until one capsule is fully visible.
2. In case a second capsule is exposed to air inadvertently this capsule has to be discarded.
3. Separate the blister strips by tearing along the perforation.
4. Remove capsule.
5. SPIRIVA capsules contain only a small amount of powder so that the capsule is only partially filled.
6. 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

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

Cleaning your HandiHaler

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

Mr. A

1. Dust cap
2. Mouthpiece
3. Base
4. Piercing button
5. Centre chamber

Boehringer Ingelheim Pharma GmbH & Co. KG
D-55216 Ingelheim am Rhein
Germany

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

1. To release the dust cap press the piercing button completely in and let go.
2. Close the mouthpiece firmly until you hear a click, leaving the dust cap open.

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

4. Hold the HandiHaler device with the mouthpiece upwards and press the piercing button only once, and release. This makes holes in the capsule and allows the medicine to be released when you breathe in.

HandiHaler® Instructions for use:

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

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

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

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. Then breathe in until your lungs are full; 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.

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.

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.

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

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

Breathe out completely.

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

Clean the HandiHaler once a month. Open the dust cap and mouthpiece. Then open the base by lifting the piercing button. Remove 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 mild but not wet tissue.
Dear Patient,

The HandiHaler enables you to inhale the medicine contained in the Spiriva capsule - that your physician has prescribed for your breathing problems.

1. Peel back foil (only immediately before use) using the tab until one capsule is fully visible.
2. Separate the blister strips by tearing along the perforation.
3. Remove capsule.

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

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 medicine. You can use your HandiHaler for up to one year to take your medicine.

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.

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

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

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

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 medicine to be released when you breathe in.

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

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

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

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

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. This takes about 5 seconds. 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.

Cleaning your HandiHaler

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.

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

Breathe out completely.

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

Clean the HandiHaler once a month. Open the dust cap and mouthpiece. Then open the base by lifting the piercing button. Remove the complete inhaler with warm water to remove any powder. Dry the HandiHaler thoroughly by helping excess of water to run off. Make sure that the mouthpiece is dry as well. Close the dust cap and mouthpiece and store 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.

Cleaning your HandiHaler

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