### What is the leaflet?
1. What Spiriva Respimat is and is used for
2. How to use Spiriva Respimat
3. What to do if you forget to use Spiriva Respimat
4. If you stop using Spiriva Respimat
5. If you have problems while using Spiriva Respimat
6. Contents of the pack and other information

### 1. What Spiriva Respimat is and is used for
- **Indication:** Spiriva Respimat is indicated for the maintenance treatment of COPD - chronic obstructive pulmonary disease - in adults. Spiriva Respimat is not recommended for the maintenance treatment of asthma.
- **Dosage:** Use once daily, at the same time each day.

### 2. How to use Spiriva Respimat
- **Instructions:** Insert the cartridge into the Spiriva Respimat inhaler. Press the button once each time you inhale to release the medication. Do not use more than twice per day.
- **Frequency:** Use once daily, except for inhaled corticosteroids or long-acting β2-agonists.

### 3. What to do if you forget to use Spiriva Respimat
- **What to do:** If you forget to use Spiriva Respimat, use it as soon as you remember. Do not use extra Spiriva Respimat to make up for the missed dose.

### 4. If you stop using Spiriva Respimat
- **What to do:** If you stop using Spiriva Respimat, talk to your doctor before you start using it again.

### 5. If you have problems while using Spiriva Respimat
- **What to do:** If you have any problems while using Spiriva Respimat, consult your doctor.

### 6. Contents of the pack and other information
- **Packaging Information:** Always use this medicine exactly as your doctor or pharmacist has prescribed. The delivery of Spiriva Respimat includes the Spiriva Respimat inhaler and the cartridge. The cartridge contains the active substance tiotropium bromide monohydrate.
- **Dosage and Administration:** Use once daily, at the same time each day. Do not use more than twice per day.

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### Possible side effects
- **Common:** Headache, nausea, vomiting, dry mouth, laryngitis, blurred vision.
- **Uncommon:** Dizziness, painful urination (dysuria), frontal headache, visual disorders, blurred vision, halos around lights.
- **Rare:** Hypersensitivity, including anaphylactic reaction.
- **Not known:** Serious allergic reaction, eye pain or discomfort, blurred vision, seeing halos around lights or sprayed colored images in association with red eyes.

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### Clinical studies
- **Observed effects:** The effects described below have been observed in clinical studies in which Spiriva Respimat was used in 1,156 patients.

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### The side effects described have been experienced by up to 1 in 100 people, and others are rare.

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### Evaluation of the side effects is based on the following frequencies:
- **Not known:** Side effects have not been observed in clinical studies.
- **Rare:** Side effects have been observed in less than 1 in 100 people.
- **Uncommon:** Side effects have been observed in 1 to 10 in 100 people.
- **Common:** Side effects have been observed in more than 10 in 100 people.

---

### 4. Possible side effects
- **Somatic effects:** Common: Headache, nausea, vomiting, dry mouth. Uncommon: Dizziness, painful urination (dysuria).
- **Eye effects:** Common: Blurred vision. Uncommon: Decreased visual acuity, coloured images in association with red eyes.
- **Other effects:** Common: Laryngitis, coughing. Uncommon: Nasal irritation, nasal congestion.

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### Driving and using machines
- **Driving and using machines:** This medicine may cause dizziness or light-headedness. Do not drive or use machines if you are affected.

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### Reporting of side effects
- **Reporting of side effects:** If you think you have a side effect, talk to your doctor or pharmacist. This includes any possible side effects, even if you are not sure it was caused by this medicine.

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### Package leaflet: Information for the user
- **What you need to know before you use Spiriva Respimat:**
- **What are COPD and asthma?** COPD is a long-term lung disease that affects the air passages and makes it difficult to breathe. Asthma is a long-term lung disease that affects the air passages and causes shortness of breath and coughing.
- **For people with COPD:** COPD is a long-term lung disease that affects the air passages and makes it difficult to breathe. Asthma is a long-term lung disease that affects the air passages and causes shortness of breath and coughing.
- **For people with asthma:** COPD is a long-term lung disease that affects the air passages and makes it difficult to breathe. Asthma is a long-term lung disease that affects the air passages and causes shortness of breath and coughing.
- **For people with both COPD and asthma:** COPD is a long-term lung disease that affects the air passages and makes it difficult to breathe. Asthma is a long-term lung disease that affects the air passages and causes shortness of breath and coughing.

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### Instructions for use
- **How to use Spiriva Respimat:** Insert the cartridge into the Spiriva Respimat inhaler. Press the button once each time you inhale to release the medication. Do not use more than twice per day.
- **Frequency:** Use once daily, at the same time each day.

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### Pregnancy and breastfeeding
- **Pregnancy:** This medicine can be used during pregnancy. However, if you are pregnant or planning to become pregnant, tell your doctor.
- **Breastfeeding:** This medicine can be used during breastfeeding. However, if you are breastfeeding, tell your doctor.

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### Evaluation of the side effects is based on the following frequencies:
- **Not known:** Side effects have not been observed in clinical studies.
- **Rare:** Side effects have been observed in less than 1 in 100 people.
- **Uncommon:** Side effects have been observed in 1 to 10 in 100 people.
- **Common:** Side effects have been observed in more than 10 in 100 people.
### Additional Requirements of Packaging site

**Technical information**

Only for BI-internal use, Template according to Drawing no.: SP-14-0090-001-B_INDEX_BLACK

**Issue date of TD:**

- a = Batch No.
- b = Expiry date

**Legend case version:**

Mat. No. Pack. Site:

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### What to do before

1. **What to do before**

   - What is in the leaflet?
   - Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
   - Before you use this medicine, read all of this leaflet and any other information supplied with it. If you have any further questions, ask your doctor or pharmacist.

2. **How to use this medicine**

   - Use this medicine exactly as described on the label or in the leaflet accompanying the pack. The manufacturer for Spiriva Respimat is: D-55216 Ingelheim am Rhein — Marketing Authorisation Holder and Manufacturer

3. **What you need to know before you use Spiriva Respimat**

   - Do not use Spiriva Respimat if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or such products.

4. **Other medicines and Spiriva Respimat**

   - If you are taking any other medicines, including non-prescription-only medicines, and herbal medicines, ask your doctor or pharmacist for advice before you take any new medicines.

5. **How to use Spiriva Respimat**

   - Always use this Medicine exactly as you have been told. If you do not understand the instructions on the label or leaflet, ask your doctor or pharmacist for help.

6. **Contents of the pack and other information**

   - Single pack: 1 Respimat re-usable inhaler and 1 cartridge, providing 60 medicinal doses
   - Triple pack: 3 Respimat re-usable inhalers and 3 cartridges, providing 60 medicinal doses
   - Do not use the Respimat re-usable inhaler for more than 6 months as the cartridge will get empty

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### How to store Spiriva Respimat

- Store below 30°C. Do not freeze.
- Store out of the reach of children.
- Keep the medicine bottle tightly closed.

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### Side effects

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Very common</th>
<th>Common</th>
<th>Uncommon</th>
<th>Rare</th>
<th>Not known</th>
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</thead>
<tbody>
<tr>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Nausea</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
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<tr>
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<td>Yes</td>
<td>Yes</td>
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<tr>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Rash</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
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</tbody>
</table>
| They may affect up to 1 in 10 people

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### How to dispose of any unused Spiriva Respimat

- Do not throw away any medicine via a sewage system or wastewater network. Clean up spills in accordance with local guidelines. Report any spills, releases or discharges to local authorities and help protect the environment.

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### Pregnancy and breastfeeding

- This medicine is not recommended for use in pregnancy. If you are pregnant or planning to become pregnant, talk to your doctor or pharmacist before using this medicine.

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### References

- The manufacturer for Spiriva Respimat is: D-55216 Ingelheim am Rhein — Marketing Authorisation Holder and Manufacturer

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Introduction

Respimat® is an inhaler device that generates a spray for inhalation.

Children should use Spiriva Respimat with an adult's assistance.

You will need to use this inhaler only ONCE A DAY. Each time you use it take TWO PUFFS.

Remove clear base

1. Keep the cap closed.
2. Press the safety catch while pulling off the clear base with your other hand.

Insert cartridge

1. Insert the cartridge into the inhaler.
2. Place the inhaler on a flat surface and push down firmly until it clicks into place.

Turn cartridge

1. Mark the check-box on inhaler's label to track the number of cartridges.
2. Put the clear base back into place until it clicks.

Open

1. Open the cap until it snaps fully open.

Press

1. Press the inhaler toward the ground.
2. Press the dose-release button twice.
3. Allow the cap to fall until it clicks to the right.
4. Repeat steps 1-3 three more times.
5. Your inhaler is now ready to use and will deliver 60 puffs (30 doses).

Prepare for use

1. Clean the clear base
2. Close the cap, so the clear base.
3. The clear base is used up. Insert a new cartridge.
4. Your Respimat re-usable is working.

Daily use

It is difficult to insert the cartridge deep enough.

1. It is difficult to insert the cartridge.
2. Insert the cartridge deep enough.

Turn, Open, Press

1. Turn the clear base in the direction of the arrows on the label until it clicks (half a turn).
2. Open the cap until it snaps fully open.

Press

1. Press the dose-release button.
2. Press the dose-release button twice.
3. Allow the cap to fall until it clicks to the right.
4. Repeat steps 1-3 three more times.
5. Your Respimat is now ready to use and will deliver 60 puffs (30 doses).

Further Information

Boehringer Ingelheim Pharma GmbH & Co. KG
D-55216 Ingelheim

When to replace the Spiriva Respimat cartridge

The dose indicator shows how many puffs remain in the cartridge.

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The dose indicator shows how many puffs remain in the cartridge.
How to care for your Spiriva Respimat re-usable

Clear the mouthpiece by shaking the inhaler with a damp cloth or tissue only once a week.

Any minor discoloration in the mouthpiece does not affect your Spiriva Respimat re-usable inhaler performance.

If necessary, wipe the outside of your Spiriva Respimat re-usable inhaler with a damp cloth.

When to replace the inhaler

When you have used an inhaler with 6 cartridges, get a new Spiriva Respimat re-usable pack containing an inhaler.