Spiriva Respimat® 2.5 microgram, solution for inhalation (tiotropium bromide)

Your medicine is available using the above name but will be referred to as Spiriva Respimat throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information about your treatment.

Keep this leaflet. You may need to read it again.

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

This leaflet has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Children and adolescents

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

Other medicines and Spiriva Respimat

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

In particular, please tell your doctor or pharmacist if you are taking/have taken anticholinergic drugs, e.g. ipratropium or otrizolam.

No interaction side effects have been reported when Spiriva Respimat has been taken with other products used to treat COPD (e.g. bronchodilators, beta-agonists, corticosteroids, theophylline).

Pregnancy and breast-feeding

If you are pregnant, do not breast-feed, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not use this medicine unless specifically recommended by your doctor.

Driving and using machines

No studies on the effects and the ability to drive and use machines have been performed. In case of dizziness or blurred vision occurs the ability to drive and use machinery may be impaired.

3. How to take Spiriva Respimat

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Spiriva Respimat is for inhalation use only.

The recommended dose for adults is: Spiriva Respimat is effective for 24 hours so you will need to use Spiriva Respimat only ONCE A DAY, if possible at the same time of the day. Each time you use Spiriva TURBO
d. As COPD and asthma are long term diseases take Spiriva Respimat every day and not only when you experience breathing problems. Do not take more than the recommended dose.

Spiriva Respimat is not recommended for use in children and adolescents below 18 years of age.

Make sure that you know how to use your Spiriva Respimat inhaler properly. The instructions for the use of the Spiriva Respimat inhaler are provided on the other side of this leaflet.

If you take more Spiriva Respimat than you should:

You may experience side effects of Spiriva Respimat. If any of these occur, please consult your doctor or pharmacist. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects not listed in this leaflet. You can also report side effects not listed in this leaflet.

Immediate allergic reactions such as rash, nettle rash (urticaria), swelling of the mouth and face or throat may occur. If these occur, stop using Spiriva Respimat and get medical help straight away.

If you stop taking Spiriva Respimat before you stop taking Spiriva Respimat, you should talk to your doctor or pharmacist.

If you forget to take Spiriva Respimat:

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Frequency of the side effects is estimated from the available data.

Side effect

Common

Uncommon

Rare

Not known

Dullness

Unc known

Unc known

Unc known

Unc known

Liver dysfunction

Not known

Not known

Not known

Not known

Liver failure

Not known

Not known

Not known

Not known

Liver jaundice

Not known

Not known

Not known

Not known

Liver disease

Not known

Not known

Not known

Not known

Liver enzyme abnormalities

Not known

Not known

Not known

Not known

Liver necrosis

Not known

Not known

Not known

Not known

Liver abscess

Not known

Not known

Not known

Not known

Liver disease due to cholestasis

Not known

Not known

Not known

Not known

Liver amyloidosis

Not known

Not known

Not known

Not known

Liver injury

Not known

Not known

Not known

Not known

Liver failure associated with jaundice

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**Spiriva® Respimat® Inhaler**

**Instructions for Use**

**Introduction**

Spiriva Respimat (tiotropium bromide). Read these Instructions for Use before you start using Spiriva Respimat.

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

- If Spiriva Respimat has not been used for more than 7 days release one puff towards the ground.
- If Spiriva Respimat has not been used for more than 21 days repeat steps 4 to 6 under ‘Prepare for first Use’ until a cloud is visible. Then repeat steps 4 to 6 three more times.
- Do not touch the piercing element inside the clear base.

**How to care for your Spiriva Respimat**

Clean the mouthpiece including the metal part inside the mouthpiece with a damp cloth or tissue only, at least once a week. Any minor discoloration in the mouthpiece does not affect your Spiriva Respimat inhaler performance. If necessary, wipe the outside of your Spiriva Respimat inhaler with a damp cloth.

**When to get a new Spiriva Respimat**

- Your Spiriva Respimat inhaler contains 60 puffs (30 doses) if used as indicated (two puffs/once daily).
- The dose indicator shows approximately how much medication is left. Your Spiriva Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Spiriva Respimat inhaler.
- Your Spiriva Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Spiriva Respimat inhaler.
- If Spiriva Respimat has not been used for more than 7 days release one puff towards the ground.
- Do not touch the piercing element inside the clear base.

**Prepare for first use**

1. **Remove clear base**
   - Keep the cap closed.
   - Press the safety catch while firmly pulling off the clear base with your other hand.

2. **Insert cartridge**
   - Insert the narrow end of the cartridge into the inhaler.

3. **Replace clear base**
   - Put the clear base back into place until it clicks.

**Spiriva Respimat locks automatically after 60 puffs (30 medicinal doses).**

**Daily Use**

- YOUR INHALER IS READY TO USE.
- These steps “OPEN” and “PRESS” are repeated until a cloud is visible. Then repeat steps 4 to 6 under “Prepare for first Use” until a cloud is visible.

1. **Turn**
   - Keep the cap closed.
   - Turn the clear base in the direction of the arrows on the label until it clicks (half a turn).

2. **Open**
   - Open the cap until it snaps fully open.

3. **Press**
   - Point the inhaler toward the ground.
   - Press the dose-release button.
   - Close the cap.
   - Repeat the steps 4 to 6 until a cloud is visible.
   - After a cloud is visible, repeat steps 4 to 6 three more times.

**Spiriva Respimat**

- Your Spiriva Respimat inhaler contains 60 puffs (30 doses) if used as indicated (two puffs/once daily).
- The dose indicator shows approximately how much medication is left.
- The Spiriva Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Spiriva Respimat inhaler.

**Answers to Common Questions**

- Is it difficult to insert the cartridge deep enough?
  - Did you accidentally turn the clear base before inserting the cartridge? Open the cap, press the dose-release button, then insert the cartridge.

- Did you insert the cartridge with the wide end first?
  - Insert the cartridge with the narrow end first.

- I cannot turn the clear base.
  - Did you turn the clear base before you inserted the cartridge?
  - Did you insert the cartridge deep enough?
  - If the clear base has already been turned, follow steps “OPEN” and “PRESS” under “Daily Use” to get your medicine.

- Is the dose indicator on the Spiriva Respimat pointing to zero?
  - The Spiriva Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Spiriva Respimat inhaler.

- The dose indicator on the Spiriva Respimat reaches zero too soon.
  - Did you use Spiriva Respimat as indicated (two puffs/once daily)? Spiriva Respimat will last 30 days if used at two puffs once daily.
  - Did you turn the clear base before you inserted the cartridge? The dose indicator counts each turn of the clear base regardless whether a cartridge has been inserted or not.
  - Did you spray in the air often to check whether the Spiriva Respimat is working? Once you have prepared Spiriva Respimat, test-spraying is required if used daily.
  - Did you insert the cartridge into a used Spiriva Respimat? Always insert a new cartridge into a NEW Spiriva Respimat.

- My Spiriva Respimat sprays automatically.
  - Was the cap open when you turned the clear base? Close the cap, then turn the clear base.
  - Did you press the dose-release button when turning the clear base? Close the cap, so the dose-release button is covered, then turn the clear base.
  - Did you stop when turning the clear base before it clicked? Turn the clear base in a continuous movement until it clicks (half a turn).

- My Spiriva Respimat doesn’t spray.
  - Did you insert a cartridge? If not, insert a cartridge.
  - Did you use Spiriva Respimat as indicated (two puffs/once daily)? Spiriva Respimat will last 30 days if used at two puffs once daily.
  - Did you turn the clear base before you inserted the cartridge? The dose indicator counts each turn of the clear base regardless whether a cartridge has been inserted or not.

**Is the dose indicator on the Spiriva Respimat pointing to 0?** If the dose indicator points to 0, you have used up all your medication and the inhaler is locked.

Once your Spiriva Respimat is assembled, do not remove the clear base or the cartridge. Always insert a new cartridge into a NEW Spiriva Respimat.