What is Striverdi Respimat and what is it used for?

Striverdi Respimat is a medicine used to help control the symptoms of chronic obstructive pulmonary disease (COPD). It includes 2 medicines: olodaterol (β2 agonist) and vilanterol (long-acting β2 agonist). These medicines open up the airways in your lungs, making it easier to breathe. Striverdi Respimat helps you breathe more easily by acting slowly on your airways to keep them open longer. It also helps on days when your airways are already feeling a bit more blocked.

How to take Striverdi Respimat

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

Striverdi Respimat is for inhalation only. Do not take it by mouth.

Swallowing the contents of the rehaler may cause serious effects. You may need urgent medical treatment.

- Immediate allergic reactions such as rash, swelling of the face and lips, or trouble breathing. Also talk to your doctor if you have symptoms of asthma.
- Uncontrolled high levels of the drug after swallowing it, causing arrhythmia (irregular heartbeat) or death

The side effects described below have been experienced by people taking this medicine and they are listed according to frequency as either common or uncommon.

- Common (affects more than 1/10 people):
  - Headache
  - Nasal irritation
  - Nasal discharge

- Uncommon (affects between 1/100 and <1/10 people):
  - Dry mouth, nausea, muscle cramps, fatigue, malaise, tremors, and rash

- Very rare (affects less than 1/1000 people):
  - Hypertension
  - Arthralgia (joint pain)
  - Rash
  - Dizziness

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

Striverdi Respimat contains 2 medicines called β2 agonists, which are medicines that open up your airways. These medicines are similar to those found naturally in your body. You can be sensitised to these medicines. Only use this medicine if your doctor has told you it is safe to do so.

Do not use Striverdi Respimat if:
- You have a history of overuse of β2 agonists (such as albuterol, salbutamol, or terbutaline)
- You have a specific thyroid gland problem called thyrotoxicosis
- You are due to have a planned surgery
- You have an aneurysm
- You have a history of asthma
- You are taking or have recently taken any other medicines.

How to store Striverdi Respimat

Keep this medicine out of the sight and reach of children. It must not be given to children under the age of 18 years.

Striverdi Respimat is a white to off-white powder in a cylindrical plastic cartridge. The cartridge has to be inserted into the inhaler. The cartridge has to be replaced every 6 weeks (or 60 puffs). Do not use the cartridge if it is more than 6 weeks old.

Do not freeze. This medicine is sensitive to high temperatures. Do not use if the cartridge has been exposed to high temperatures, such as from being left in a locked car on a hot day.

How to handle and store Striverdi Respimat

- Use the inhaler immediately after removing the protective cap.
- Do not give more than 1 inhalation at a time.
- Do not take a double dose to make up for a forgotten dose.
- Do not use if the cartridge has been exposed to high temperatures.

Procurement, storage and handling

If you are pregnant or breast-feeding, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Storage and driving machines

Driving: If you experience any side effects affecting your reaction time, you should not drive or use any tools or machines until you feel better. This includes any possible side effects not listed in this leaflet.

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Striverdi Respimat
®
2.5 microgram, inhalation solution (solution)

1. What Striverdi Respimat is and what it is used for
Striverdi Respimat helps people who have chronic obstructive pulmonary disease (COPD) to breathe more comfortably and easily. The main COPD symptoms are: breathlessness (dyspnoea), coughing (expectoration) and regular wheezing (bronchospasm). Striverdi Respimat contains the active substance levalbuterol (a short-acting beta 2 agonist). It is a combination of a prolonged release component and an immediate release component. The delivered dose is the dose which is available for the patient to use. This can be calculated by the machine. The dose is set to 4 puffs at the start of each treatment, and the dose can be adjusted at the discretion of the healthcare provider. This product is not intended for use in children under the age of 18 years.

2. How to take Striverdi Respimat
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Striverdi Respimat is for inhalation use only.

3. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects of Striverdi Respimat are: throat irritation, dry mouth, shortness of breath, headache.

4. Possible side effects
Possible side effects are:

Side effects which may need medical treatment:

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1. What Striverdi Respimat is and what it is used for

Striverdi Respimat helps people with chronic obstructive pulmonary disease (COPD) to breathe more comfortably.

1.3. What Striverdi Respimat contains

Striverdi Respimat contains the active substance olodaterol.

1.4. How Striverdi Respimat works

Striverdi Respimat contains an active substance that helps to open your airways. The medicine is inhaled through a mouthpiece. The medicine works in the lung for 12 hours.

1.5. How to use Striverdi Respimat

Striverdi Respimat is for inhalation use only.

3. What you need to know before you take Striverdi Respimat

3.1. Why Striverdi Respimat has been prescribed for you

This medicine has been prescribed for you only.

3.2. What you should do if you have problems

If you experience any side effects affecting your heart, call your doctor or pharmacist for advice before taking this medicine.

3.3. What you should do if you experience side effects

If you experience any side effects, talk to your doctor or pharmacist for advice before taking this medicine.

3.4. How to use Striverdi Respimat

You should use Striverdi Respimat to treat your condition. You should use Striverdi Respimat for as long as your doctor or pharmacist tells you.

3.5. How to take Striverdi Respimat

Always follow this medicine as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

3.6. Possible side effects

Like many medicines, this medicine can cause side effects, although not everybody gets them.

4. Possible side effects

This medicine can cause side effects, although not everybody gets them. If you experience any side effects, talk to your doctor or pharmacist for advice before taking this medicine.

5. How to store Striverdi Respimat

This medicine should be stored below 25°C.

6. Contents of the pack and other information

Packaging information.

The medicinal product is authorized in the Member States of the EEA under the following names:

Austria: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Belgium: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Bulgaria: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Croatia: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Cyprus: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Czech Republic: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Denmark: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Estonia: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Finland: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
France: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Germany: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Greece: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Hungary: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Ireland: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Italy: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Latvia: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Lithuania: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Luxembourg: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Netherlands: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Norway: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Poland: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Portugal: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.
Romania: Striverdi Respimat, Almirall; Striverdi Respimat, LEO.

Further information on the medicines is available from Lexchin website www.lix.ch.
Striverdi Respimat®

Instructions For Use

How to care for your Striverdi Respimat

Preparation of the inhaler

To use your Striverdi Respimat® inhaler, you should:

1. Remove clear base
2. Insert cartridge
3. Replace clear base
4. Press button

Before first use

Before using your Striverdi Respimat for the first time, you should:

1. Turn the clear base
2. Press button
3. Open cap
4. Press button

How to use your Striverdi Respimat

To use your Striverdi Respimat for the first time, you should:

1. Turn the clear base
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3. Open cap
4. Press button

Daily use

To use your Striverdi Respimat on a daily basis, you should:

1. Turn the clear base
2. Press button
3. Open cap
4. Press button

Answers to Common Questions

1. Why doesn’t spray.
   - Striverdi Respimat® does not spray. It is a dry powder inhaler.
2. My Striverdi Respimat medication and the inhaler is... time under “Prepare for first use.”
   - Once your Striverdi Respimat is ready, follow the steps under “Daily Use” to get your medicine.
3. Did you repeat TURN, OPEN, PRESS less than three times after inserting the cartridge? Did you use your new Striverdi Respimat pointing to...
   - If the dose indicator is not zero, insert a cartridge.
4. I cannot press the dose-release button.
   - If the dose indicator shows approximately how much medication is left.
5. Is the dose indicator on the Striverdi Respimat pointing to...
   - If the clear base has already been turned, follow the steps under “Daily Use” to get your medicine.
6. Did you accidentally turn the clear base before inserting the cartridge?
   - Did you repeat TURN, OPEN, PRESS less than three times after inserting the cartridge?
7. I cannot turn the clear base.
   - Did you use Striverdi Respimat as indicated (two puffs/Once...
8. Keep the cap closed.
   - Keep the cap closed.
9. Did you use Striverdi Respimat 60 times after you have prepared it for first use, ... at least once a week.
10. Striverdi Respimat should be discarded three months after you have prepared it for first use, even if it has not been fully used or used at all.
11. Your Striverdi Respimat contains 60 puffs (stats) if used as indicated (twice per day).
**Prepare for first use**

1. **Remove clear base:**
   - Keep the cap closed.
   - Place the inhaler so that the clear base is facing upward.
   - Press the dose-release button.
   - The dose indicator resets to zero.

2. **Insert cartridge:**
   - Place the inhaler so that the arrows on the label are facing upward.
   - Press the dose-release button.
   - The dose indicator resets to zero.

3. **Replace clear base:**
   - Place the clear base back into place and flip it upward.

4. **Turn:**
   - Keep the cap closed.
   - Press the dose-release button three times.
   - The dose indicator resets to zero.

5. **Open:**
   - Open the cap and let it snap fully open.

6. **Press:**
   - Press the dose-release button three times.
   - The dose indicator resets to zero.

**Daily use**

- **Daily use**:
  - Do not to turn the clear base and press the dose-release button if the dose indicator points to zero.
  - If the dose indicator points to zero, insert a new cartridge.
  - The dose indicator points to zero?
  - Is the dose indicator on the clear base?
  - If the clear base has already?
  - Did you turn the clear base?
  - Did you turn the clear base?
  - Did you turn the clear base?

**Answers to Common Questions**

- **Questions**:
  - Why does my Striverdi Respimat not spray?
  - My Striverdi Respimat sprays and the inhaler is locked.
  - Always insert a new cartridge into your Striverdi Respimat.

- **Instructions**:
  - Check whether the Respimat Respimat is pointing to zero?
  - If the Respimat Respimat pointing to zero?
  - Is the dose indicator on the clear base?

- **Limitations**:
  - If you use the Respimat Respimat pointing to zero?
  - Is the dose indicator on the clear base?