Medication Guide STRIVERDI[®] RESPIMAT[®] (STRIH ver dee – RES peh mat)

(olodaterol) inhalation spray

Read the Medication Guide that comes with STRIVERDI RESPIMAT before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about STRIVERDI RESPIMAT?

STRIVERDI RESPIMAT has been approved for chronic obstructive pulmonary disease (COPD) only. STRIVERDI RESPIMAT is <u>NOT</u> to be used in asthma.

STRIVERDI RESPIMAT can cause serious side effects, including:

- People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines, such as STRIVERDI RESPIMAT, have an increased risk of death from asthma problems.
- It is not known if LABA medicines, such as STRIVERDI RESPIMAT, increase the risk of death in people with COPD.
- Get emergency medical care if:
 - $_{\circ}$ breathing problems worsen quickly
 - $_{\circ}$ you use your rescue inhaler medicine, but it does not relieve your breathing problems

What is STRIVERDI RESPIMAT?

STRIVERDI RESPIMAT is used long term, 1 time each day, in controlling symptoms of COPD in adults with COPD.

LABA medicines such as STRIVERDI RESPIMAT help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath.

STRIVERDI RESPIMAT is not for use to treat sudden symptoms of COPD. Always have a rescue medicine with you to treat sudden symptoms. If you do not have a rescue inhaler, contact your healthcare provider to have one prescribed for you.

It is not known if STRIVERDI RESPIMAT is safe and effective in people with asthma.

STRIVERDI RESPIMAT should not be used in children. It is not known if STRIVERDI RESPIMAT is safe and effective in children.

Who should not use STRIVERDI RESPIMAT?

Do not use STRIVERDI RESPIMAT if you have asthma.

What should I tell my healthcare provider before using STRIVERDI RESPIMAT?

Tell your healthcare provider about all of your health conditions, including if you:

- have heart problems
- have high blood pressure

- have seizures
- have thyroid problems
- have diabetes
- are pregnant or planning to become pregnant. It is not known if STRIVERDI RESPIMAT can harm your unborn baby.
- are breastfeeding. It is not known if STRIVERDI RESPIMAT passes into your breast milk and if it can harm your baby.
- are allergic to STRIVERDI RESPIMAT or any of its ingredients, any other medicines, or food products.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. STRIVERDI RESPIMAT and certain other medicines may interact with each other. This may cause serious side effects.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use STRIVERDI RESPIMAT?

- The STRIVERDI RESPIMAT inhaler has a slow-moving mist that helps you inhale the medicine.
- Read the step-by-step instructions for using STRIVERDI RESPIMAT at the end of this Medication Guide.
- Use STRIVERDI RESPIMAT exactly as your healthcare provider tells you to use it.
- Use 1 dose (2 puffs) of STRIVERDI RESPIMAT, 1 time each day, at the same time of the day.
- If you miss a dose of STRIVERDI RESPIMAT, take it as soon as you remember. Do not take more than 1 dose (2 puffs) in 24 hours.
- Do not spray STRIVERDI RESPIMAT in your eyes.
- Always use the new STRIVERDI RESPIMAT inhaler that is provided with each new prescription.
- **STRIVERDI RESPIMAT does not relieve sudden symptoms of COPD.** Always have a rescue inhaler medicine with you to treat sudden symptoms. If you do not have a rescue inhaler medicine, call your healthcare provider to have one prescribed for you.
- Do not stop using STRIVERDI RESPIMAT or other medicines to control or treat your COPD unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- Do not use STRIVERDI RESPIMAT:
 o more often than prescribed for you, or
 o with other LABA medicines
- Call your healthcare provider or get emergency medical care right away if: • your breathing problems worsen with STRIVERDI RESPIMAT
 - ° you need to use your rescue medicine more often than usual
 - your rescue inhaler medicine does not work as well for you at relieving your symptoms

What are the possible side effects with STRIVERDI RESPIMAT?

STRIVERDI RESPIMAT can cause serious side effects, including:

 See "What is the most important information I should know about STRIVERDI RESPIMAT?"

- If your COPD symptoms worsen over time do not increase your dose of STRIVERDI RESPIMAT, instead call your healthcare provider.
- sudden shortness of breath that may be life-threatening
- fast or irregular heartbeat, palpitations
- chest pain
- increased blood pressure
- low blood potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm)
- high blood sugar
- serious allergic reactions including rash, hives, swelling of the face, mouth, and tongue, and breathing problems. Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction.

Common side effects of STRIVERDI RESPIMAT include:

- runny nose
- upper respiratory infection
- bronchitis
- urinary tract infection
- cough
- dizziness
- rash
- diarrhea
- back pain
- joint pain

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects with STRIVERDI RESPIMAT. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store STRIVERDI RESPIMAT?

- Store STRIVERDI RESPIMAT at room temperature 68°F to 77°F (20°C to 25°C).
- Do not freeze your STRIVERDI cartridge or RESPIMAT inhaler.
- Keep your STRIVERDI RESPIMAT and all medicines out of the reach of children.

General Information about safe and effective use of STRIVERDI RESPIMAT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use STRIVERDI RESPIMAT for a condition for which it was not prescribed. Do not give STRIVERDI RESPIMAT to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about STRIVERDI RESPIMAT. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about STRIVERDI RESPIMAT that was written for healthcare professionals.

For more information about STRIVERDI RESPIMAT or a video demonstration on how to use STRIVERDI RESPIMAT, go to <u>www.STRIVERDI.com</u>, or scan the code below. You may also call 1-800-542-6257 or (TTY) 1-800-459-9906 for further information about STRIVERDI RESPIMAT.



What are the ingredients in STRIVERDI RESPIMAT?

Active ingredient: Olodaterol

Inactive ingredients: water, benzalkonium chloride, edetate disodium, and anhydrous citric acid