

PATIENT INFORMATION
STRIVERDI® RESPIMAT® (STRIH ver dee– RES peh mat)
(olodaterol inhalation spray), for oral inhalation use

What is STRIVERDI RESPIMAT?

- STRIVERDI RESPIMAT is a long-acting beta₂-adrenergic agonist (LABA) medicine, olodaterol.
- 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. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.
- STRIVERDI RESPIMAT is for long-term use and should be taken as 2 puffs 1 time each day to improve the symptoms of COPD for better breathing.
- STRIVERDI RESPIMAT is a prescription medicine used to control the symptoms of COPD in adults with COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both.
- **STRIVERDI RESPIMAT is not used to treat sudden symptoms of COPD.** Always have a beta₂-agonist inhaler medicine (rescue inhaler) with you to treat sudden symptoms of COPD. If you do not have a rescue inhaler medicine, contact your healthcare provider to have one prescribed for you.
- **STRIVERDI RESPIMAT is not for the treatment of asthma. 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.**

Do not use STRIVERDI RESPIMAT if you have asthma.

Before you use STRIVERDI RESPIMAT, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- have high blood pressure.
- have seizures.
- have thyroid problems.
- have diabetes.
- are pregnant or plan to become pregnant. It is not known if the medicine olodaterol in STRIVERDI RESPIMAT can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if the medicine olodaterol in STRIVERDI RESPIMAT passes into your breast milk and if it can harm your baby. You and your healthcare provider should decide if you will take STRIVERDI RESPIMAT while breastfeeding.
- are allergic to any of the ingredients in STRIVERDI RESPIMAT, 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 affect 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?

Read the step-by-step instructions for using STRIVERDI RESPIMAT at the end of this Patient Information leaflet.

- **Do not** use STRIVERDI RESPIMAT unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly. Ask your healthcare provider or pharmacist if you have any questions.
- The STRIVERDI RESPIMAT inhaler has a slow moving mist that helps you inhale the medicine.
- Use STRIVERDI RESPIMAT exactly as your healthcare provider tells you to use it. **Do not use STRIVERDI RESPIMAT more often than prescribed.**
- **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.
- **If you take too much STRIVERDI RESPIMAT, call your healthcare provider or go to the nearest hospital emergency room right away.**
- **Do not spray STRIVERDI RESPIMAT in your eyes.**
- STRIVERDI RESPIMAT Inhalation Spray should only be given using the STRIVERDI RESPIMAT inhaler. The STRIVERDI RESPIMAT inhaler should not be used to give other medicines.
- Always use the new STRIVERDI RESPIMAT inhaler that is provided with each new prescription.
- **STRIVERDI RESPIMAT does not relieve sudden symptoms of COPD. You should not take extra doses of STRIVERDI RESPIMAT to 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.
- If your COPD symptoms worsen over time do not increase your dose of STRIVERDI RESPIMAT, instead call your healthcare provider.
- **Do not use STRIVERDI RESPIMAT:**
 - more often than prescribed for you,
 - at a higher dose than prescribed for you, or
 - with other LABA medicines. Ask your healthcare provider or pharmacist if any of your other medicines are 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 inhaler medicine more often than usual, or your rescue inhaler medicine does not work as well for you at relieving your symptoms.

What are the possible side effects of STRIVERDI RESPIMAT?

STRIVERDI RESPIMAT can cause serious side effects, including:

- **serious problems from asthma.** People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines, such as STRIVERDI RESPIMAT, without also using a medicine called an inhaled corticosteroid, have an increased risk of serious problems from asthma, including being hospitalized, needing a tube placed in their airway to help them breathe, or death.
- **call your healthcare provider if breathing problems worsen over time while using STRIVERDI RESPIMAT.** You may need a different treatment.
- **Get emergency medical care if:**
 - your breathing problems worsen quickly
 - you use your rescue inhaler medicine, but it does not relieve your breathing problems.
- **using too much of a LABA medicine may cause:**
 - chest pain
 - fast and irregular heartbeat
 - tremor
 - increased blood pressure
 - headache
 - nervousness
- **COPD symptoms can get worse over time.** If your COPD symptoms worsen over time, do not increase your dose of STRIVERDI RESPIMAT, instead call your healthcare provider.
- **sudden shortness of breath can happen immediately after using STRIVERDI RESPIMAT.** Sudden shortness of breath may be life-threatening. Stop taking STRIVERDI RESPIMAT and call your healthcare provider or get emergency medical help right away if you get sudden shortness of breath after using STRIVERDI RESPIMAT.
- **effects on your heart,** including fast or irregular heartbeat, palpitations, chest pain or increased blood pressure.
- **changes in laboratory blood levels including high blood sugar (hyperglycemia) and low levels of potassium (hypokalemia),** which may cause symptoms of muscle weakness or abnormal heart rhythm.
- **serious allergic reactions including rash, hives, itching, swelling of the face, lips, tongue, throat, difficulties in breathing or swallowing.** Stop taking STRIVERDI RESPIMAT and get emergency medical help right away if you get any symptoms of a serious allergic reaction after using STRIVERDI RESPIMAT.

Common side effects of STRIVERDI RESPIMAT include: runny nose, sore throat, upper respiratory infection, bronchitis, urinary tract infection, cough, dizziness, rash, diarrhea, back pain, and joint pain.

These are not all the side effects of STRIVERDI RESPIMAT. 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, between 68°F to 77°F (20°C to 25°C).
- **Do not** freeze your STRIVERDI cartridge or RESPIMAT inhaler.
- **Keep STRIVERDI RESPIMAT inhaler, cartridge, 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 Patient Information leaflet. 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 symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about STRIVERDI RESPIMAT that is written for health professionals.

Active ingredient: olodaterol

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

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This product's label may have been updated. For current full prescribing information for STRIVERDI RESPIMAT, go to www.STRIVERDI.com or to view a video demonstration on how to use your STRIVERDI RESPIMAT inhaler, scan the code below or visit www.themist.com. You may also call 1-800-542-6257 or (TTY) 1-800-459-9906 for further information about STRIVERDI RESPIMAT.

