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Olodaterol Mist

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Description

Side Effects Nervousness, shaking (tremor), and trouble sleeping may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high. Tell your doctor right away if you have any serious side effects, including: pounding heartbeat, muscle cramps/weakness, increased thirst/urination, joint pain. Get medical help right away if you have any very serious side effects, including: chest pain, rapid breathing, fast/irregular heartbeat, severe dizziness, fainting. Rarely, this medication has caused severe (possibly fatal), sudden worsening of breathing problems (paradoxical bronchospasm). If you have trouble breathing or sudden wheezing, use your quick-relief inhaler and get medical help right away. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses Olodaterol is used as a long-term (maintenance) treatment to prevent and decrease wheezing and shortness of breath caused by breathing problems (such as chronic obstructive pulmonary disease, including chronic bronchitis and emphysema). Olodaterol belongs to the class of drugs known as long-acting beta agonists (LABAs). Olodaterol is also known as a bronchodilator. It works by relaxing the muscles around the airways so that they open up and you can breathe more easily. Controlling symptoms of breathing problems can decrease time lost from work or school. This medication does not work right away and should not be used for sudden attacks of breathing trouble. Your doctor must prescribe a quick-relief medicine/inhaler (such as albuterol, also known as salbutamol) for sudden shortness of breath while you are using olodaterol. You should always have a quick-relief inhaler with you. Olodaterol is not approved to treat asthma. People with asthma using long-acting inhaled beta agonists (such as olodaterol) without also using an inhaled corticosteroid may have an increased risk of serious (sometimes fatal) breathing problems. How to use Olodaterol Mist Read the Patient Information Leaflet provided by your pharmacist before you start using this medication and each time you get a refill. Follow the illustrated directions for the proper use of this

medication. If you have any questions, ask your doctor or pharmacist. Follow the instructions for priming the inhaler if you are using it for the first time, or if you have not used it for a long time (such as more than 3 days or 21 days). When priming the inhaler, make sure to spray toward the ground (away from the face) so that you do not get the medication into your eyes. Inhale this medication by mouth as directed by your doctor, usually once daily. Wait at least 1 minute between each inhalation. If you are using other inhalers at the same time, wait at least 1 minute between the use of each medication. Do not use more of this medication or use it more often than prescribed since this may cause serious side effects. Do not use more than 2 inhalations of olodaterol a day. Use this medication regularly to get the most benefit from it. To help you remember, use it at the same time each day. Do not stop taking this medication without consulting your doctor. If you have been using a quick-relief inhaler (albuterol, salbutamol) on a regular daily schedule (such as 4 times daily), your doctor will direct you to stop this schedule and only use the quick-relief inhaler as needed for sudden shortness of breath. Consult your doctor for details. Learn which of your inhalers you should use every day and which you should use if your breathing suddenly worsens (quick-relief drugs). Ask your doctor ahead of time what you should do if you have new or worsening cough or shortness of breath, wheezing, increased sputum, waking up at night with trouble breathing, if you use your quick-relief inhaler more often, or if your quick-relief inhaler does not seem to be working well. Learn when you can treat sudden breathing problems by yourself and when you must get medical help right away. Tell your doctor if your symptoms do not improve or if they worsen.

Precautions Before taking olodaterol, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart problems (such as irregular heartbeat, angina, previous heart attack), high blood pressure, diabetes, seizures, overactive thyroid (hyperthyroidism). Olodaterol may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using olodaterol, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using olodaterol safely. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Older adults may be more sensitive to the side effects of this drug, especially QT prolongation (see above). During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. It is unknown if this medication passes into breast milk. Consult your doctor before breast-feeding.

Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: chest pain, fast/irregular heartbeat, severe dizziness, fainting. Do not share this medication with others. Lab and/or medical tests (such as blood pressure, heart rate, lung function) should be done while you are using this medication. Keep all medical and lab appointments. Consult your doctor for more details. Avoid substances that can worsen breathing problems by causing irritation or allergic reactions, such as smoke, pollen, pet dander, dust, and mold. Because the flu virus can worsen breathing problems, ask your doctor or pharmacist if you should have a flu shot every year. If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Use your next dose at the regular time. Do not double the dose to catch up. Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and

share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Do not use other LABA drugs (such as formoterol, salmeterol) while using this medication.

Side Effects

Uses

Interactions

Other Details
