

# Brightside Specialty Pharmacy

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## Patient Education for STIOLTO RESPIMAT INHAL SPRAY

Do not use more often than recommended by doctor. Instruct patient proper administration technique. Dispense Medication Guide and explain to patient before use. May cause dizziness. Use caution operating machinery or driving. QT prolongation risk. Tell patient to report symptoms to doctor ASAP. Avoid smoking, smoke, irritants, and allergens. Not intended to be used for rescue during acute breathing trouble. Tell Dr. if breathing not controlled &/or using more bronchodilator.

Do not use more often than recommended by Dr. Know how to use before taking. Before use, important to read the Medication Guide. May make you dizzy. Use caution when driving. Tell doctor if fainting or faintness occurs. Avoid smoking, allergens, smoke and irritants. Will not stop sudden breathing trouble. Use daily. Tell Dr. if using rescue inhaler more & more often.

### .....Education Section.....

#### **IMPORTANT:**

**HOW TO USE THIS INFORMATION:** This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

**TIOTROPIUM/OLODATEROL - INHALATION**

(TYE-oh-TROE-pee-um/OH-loe-DA-ter-ol)

#### **COMMON BRAND NAME(S):**

Stiolto Respimat

#### **USES:**

This product is used to control and prevent symptoms (such as wheezing and shortness of breath) caused by ongoing lung disease (chronic obstructive pulmonary disease-COPD, which includes chronic bronchitis and emphysema). Controlling symptoms of breathing problems helps you stay active. This inhaler contains 2 medications: tiotropium and olodaterol. Both drugs work by relaxing the muscles around the airways so that they open up and you can breathe more easily. Tiotropium belongs to a class of drugs known as anticholinergics. Olodaterol belongs to the class of drugs known as long-acting inhaled beta-agonists (LABAs). Both drugs are also known as bronchodilators.

This medication must be used regularly to be effective. It does not work right away and should not be used to relieve sudden shortness of breath. If sudden breathing problems occur, use your quick-relief inhaler as prescribed.

Tiotropium/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:**

Read the Patient Information Leaflet and

Instructions for Use provided by your pharmacist before you start using this medication and each time you get a refill. 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 more than 3 days, or for more than 21 days. When priming the inhaler, make sure to spray toward the ground (away from your face) so that you do not get the medication in your eyes.

Inhale this medication by mouth as directed by your doctor, usually 2 puffs once daily. Wait at least 1 minute between each inhalation.

If you are using other inhalers at the same time, wait at least one minute between the use of each medication.

Use this medication regularly to get the most benefit from it. Use it at the same time each day. Do not use it more than one time each day.

Do not increase your dose, use this medication more often, or stop using it without first consulting your doctor. Your condition will not improve any faster, and your risk of side effects will increase.

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.

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.

Tell your doctor if your condition does not improve or if it worsens.

#### **SIDE EFFECTS:**

Nervousness, shaking (tremor), or 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: muscle cramps/weakness, increased thirst/urination, difficult/painful urination.

Get medical help right away if you have any very serious side effects, including: chest pain, fast/irregular heartbeat, severe dizziness, fainting, eye pain/swelling/redness, vision changes (such as seeing rainbows around lights at night, blurred vision).

Rarely, this medication may cause sudden, severe wheezing/trouble breathing right after you use it. If this happens, 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](http://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.

#### **PRECAUTIONS:**

Before using this product, tell your doctor or

pharmacist if you are allergic to tiotropium or olodaterol; or to ipratropium; 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 chest pain, irregular heartbeat, previous heart attack), high blood pressure, diabetes, kidney disease, personal or family history of glaucoma (angle-closure type), seizures, overactive thyroid, difficulty urinating (such as due to an enlarged prostate).

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 this medication 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.

#### **DRUG 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 arformoterol, salmeterol) while using this medication.

#### **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.

#### **NOTES:**

Do not share this medication with others.

Laboratory and/or medical tests (such as blood pressure, pulse, lung function) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

Avoid substances that can worsen breathing problems by causing irritation or allergic reaction, 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 get a flu shot every year.

#### **MISSED DOSE:**

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.

#### **STORAGE:**

Store at room temperature away from light and moisture.

Do not freeze. 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.

**MEDICAL ALERT:**

Your condition can cause complications in a

medical emergency. For information about enrolling in MedicAlert, call 1-888-633-4298 (US) or 1-800-668-1507 (Canada).

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