

Brightside Specialty Pharmacy

431 N. Tustin Ave., STE C, Santa Ana, CA 92705

Phone 714-707-5115

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Patient Education for TRELEGY ELLIPTA 100-62.5-25

.....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.

FLUTICASONE/UMECLIDINIUM/VILANTEROL POWDER - ORAL INHALATION

(floo-TIK-a-son/ue-ME-kli-DIN-ee-um/vye-LAN-ter-ol)

COMMON BRAND NAME(S):

Trelegy Ellipta

USES:

This product is used to control and prevent symptoms (such

as wheezing and shortness of breath) caused by asthma and 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 3 medications: fluticasone, umeclidinium, and vilanterol. Fluticasone belongs to a class of drugs known as corticosteroids. It works by reducing swelling of the airways in the lungs to make breathing easier. Umeclidinium belongs to a class of drugs known as anticholinergics and vilanterol is a LABA medication. Both drugs work by relaxing the muscles around the airways so that they open up and you can breathe more easily. Both drugs are also known as bronchodilators.

When used alone, long-acting beta agonists (such as vilanterol) may rarely increase the risk of serious (sometimes fatal) asthma-related breathing problems. However, combination products containing both an inhaled corticosteroid and long-acting beta agonist, such as this product, do not increase the risk of serious asthma-related breathing problems. For asthma treatment, this product should be used when breathing problems are not well controlled with two asthma-control medications (such as inhaled corticosteroid and long-acting beta agonist) or if your symptoms need combination treatment.

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.

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. Follow the illustrated directions for the proper use of this medication. If you have any questions, ask your doctor or pharmacist.

Inhale this medication by mouth as directed by your doctor, usually once daily. Do not open the cover of the inhaler until you are ready to use it. Each time you open the cover, you prepare a dose of the medication. If you open and close the cover without inhaling the medication, you will lose the dose. To avoid wasting a dose, do not close the cover until after you have inhaled the medication. You may or may not taste/feel the drug when you inhale. Do not exhale into the device.

Use this medication regularly to get the most benefit from it. To help you remember, use it at the same time every 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.

To prevent dry mouth, hoarseness, and oral yeast infections from developing, gargle, rinse your mouth with water and spit out after each use. Do not swallow the rinse water.

If you are using other inhalers at the same time, wait at least 1 minute between the use of each medication.

If you have been using a quick-relief inhaler (such as albuterol, also called salbutamol in some countries) on a regular daily schedule (such as 4 times daily), you must 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.

If you are regularly taking corticosteroids by mouth (such as prednisone), continue to follow your doctor's instructions on taking them. Do not stop taking them. Your doctor may want you to reduce your dose gradually.

Tell your doctor if your condition does not get better or if it gets worse.

SIDE EFFECTS:

Dry/irritated throat, hoarseness, or coughing may

occur as your body adjusts to the medication. 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.

Tell your doctor right away if you have any serious side effects, including: white patches in your mouth or on your tongue, signs of infection (such as sore throat that doesn't go away, fever, chills), increased thirst/urination, bone pain, difficult/painful urination, shaking (tremor), muscle cramps/weakness, mental/mood changes (such as depression, mood swings, nervousness, agitation), easy bruising/bleeding.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

Rarely, this medication may cause sudden, severe wheezing/trouble breathing immediately after you use it. If this happens, use your quick-relief inhaler and get medical help right away.

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).

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.

PRECAUTIONS:

Before using this medication, tell your doctor or

pharmacist if you are allergic to fluticasone, umeclidinium, or vilanterol, or if you have any other allergies. This product may contain inactive ingredients (such as milk proteins), 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: current/past infections (such as tuberculosis, herpes), heart problems (such as chest pain, irregular heartbeat), high blood pressure, bone loss (osteoporosis), personal or family history of eye problems (such as cataracts, glaucoma), difficulty urinating (such as due to an enlarged prostate), seizures, overactive thyroid, diabetes, liver disease.

This product 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 this product, 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 product safely.

This product can make you more likely to get infections or may worsen any current infections. Avoid contact with people who have infections that may spread to others (such as chickenpox, measles, flu). Consult your doctor if you have been exposed to an infection or for more details.

If you have switched from a corticosteroid taken by mouth (such as prednisone tablets) to this inhaler within the past 12 months, or if you have been using this product in higher-than-usual doses for a long time, it may be more difficult for your body to respond to physical stress. Before having surgery or emergency treatment, or if you get a serious illness/injury, tell your doctor or dentist that you are using this medication or have used a corticosteroid taken by mouth within the past 12 months. Tell your doctor right away if you develop unusual/extreme tiredness or weight loss. Carry a warning card or medical ID bracelet that says you use (or have used) corticosteroid medications.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This medication may temporarily slow down a child's growth if used for a long time. However, poorly controlled asthma can also slow down growth. See the doctor regularly so your child's height can be checked.

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.

Other medications can affect the removal of fluticasone from your body, which may affect how fluticasone works. Examples include HIV protease inhibitors (such as lopinavir, ritonavir), some azole antifungals (such as ketoconazole), among others.

Do not use other anticholinergic drugs (such as ipratropium, tiotropium) or LABA drugs (such as formoterol, 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: shaking (tremor), chest pain, fast/irregular heartbeat, seizures.

NOTES:

Do not share this medication with others.

Lab and/or medical tests (such as cortisol levels, lung function, blood pressure, pulse/heart rate, eye exams) should be done while you are using this medication. Keep all medical and lab appointments. Consult your doctor for more details.

Avoid smoking and other things that can worsen breathing problems. Because the flu virus can also worsen breathing problems, ask your doctor or pharmacist if you should have a flu shot every year.

In adults, this medication can increase the risk of bone loss (osteoporosis) if used for a long time. Talk with your doctor about your risk, and about available treatments for osteoporosis. Lifestyle changes that help promote healthy bones include increasing weight-bearing exercise, stopping smoking, limiting alcohol, and eating well-balanced meals that contain adequate calcium and vitamin D. You may also need to take calcium and vitamin D supplements. Consult your doctor for specific advice. To help prevent osteoporosis later in life, encourage children to exercise and eat a healthy diet (including calcium).

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. Do not use more than one dose each day.

STORAGE:

Store at room temperature away from light, heat, and

moisture. Do not store in the bathroom. Do not open the sealed tray that the inhaler comes in until you are ready to use the new inhaler. Throw away the inhaler 6 weeks after first removing it from the tray or when the dose counter reads zero, whichever comes first. 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). Information last revised April 2022. Copyright(c) 2022 First Databank, Inc.