

Brightside Specialty Pharmacy

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

Phone 714-707-5115

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Patient Education for BREO ELLIPTA 100-25 MCG INH

Physician must know patient's complete medical history Do not use more often than recommended by doctor Rinse mouth with water after dose; Do not swallow water Instruct patient proper administration technique Dispense Medication Guide and explain to patient before use QT prolongation risk. Tell patient to report symptoms to doctor ASAP Not intended to be used for rescue during acute breathing trouble Tell Dr. if breathing not control- led &/or using more bronchodilator

Tell doctor your complete medical history Do not use more often than recommended by Dr. Rinse mouth with water & spit out after dose Know how to use before taking. Before use, important to read the Medication Guide Tell doctor if fainting or faintness occurs. 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.

FLUTICASONE/VILANTEROL POWDER INHALER - ORAL INHALATION

(floo-TIK-a-son/vye-LAN-ter-ol)

COMMON BRAND NAME(S):

Breo Ellipta

USES:

This medication is used to prevent and decrease symptoms

(wheezing and trouble breathing) caused by asthma and ongoing lung disease (chronic obstructive pulmonary disease-COPD, including chronic bronchitis and emphysema). This inhaler contains 2 medications: fluticasone and vilanterol. Fluticasone belongs to a class of drugs known as corticosteroids. It works by reducing the swelling of the airways in the lungs to make breathing easier. Vilanterol belongs to a class of drugs known as long-acting beta agonists. It works by relaxing the muscles around the airways so that they open up and you can breathe more easily.

When used alone, long-acting beta agonists (like vilanterol) may rarely increase the risk of serious (sometimes fatal) asthma-related breathing problems. However, combination inhaled corticosteroid and long-acting beta agonists, 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 one asthma-control medication (such as inhaled corticosteroid) or if your symptoms need combination treatment.

Before using this medication, it is important to learn how to use it properly. This medication must be used regularly to be effective. It does not work right away and should not be used to

relieve sudden asthma attacks. If an asthma attack occurs, use your quick-relief inhaler (such as albuterol, also called salbutamol in some countries) 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 use more than 1 inhalation daily. If you open and close the cover without inhaling this medication, you will lose the dose. If this happens, you should load a new dose and inhale it.

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 it as needed for sudden shortness of breath. Contact your doctor for details.

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

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.

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 increase your dose, use this medication more often, or stop using it without talking to your doctor. Also, do not use other long-acting beta agonists while using this medication.

If this medication stops working well, or you need to use your quick-relief inhaler more often than usual (4 or more puffs daily or use of more than 1 inhaler every 8 weeks), get medical help right away. It may be a sign of worsening asthma or COPD, which is a serious condition.

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.

It may take several weeks or longer before you get the full benefit of this drug. Tell your doctor if your condition does not improve or if it worsens.

SIDE EFFECTS:

See also Precautions section.

Headache, dry/irritated throat, hoarseness, runny nose, and 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, weakness, puffy face, unusual weight gain, slow wound healing, thinning skin, bone pain, menstrual period changes, mental/mood changes (such as depression, nervousness, mood swings, agitation), easy bruising/bleeding, increased thirst/urination, vision problems, muscle cramps, shaking (tremor), signs of infection (such as sore throat that doesn't go away, fever, chills, cough).

Get medical help right away if you have any very serious side effects, including: fast/irregular heartbeat, severe dizziness, fainting, chest pain.

Rarely, this medication has caused severe (rarely fatal), sudden worsening of breathing problems (paradoxical bronchospasm). If you have trouble breathing, 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.

PRECAUTIONS:

Before using this medication, tell your doctor or

pharmacist if you are allergic to fluticasone 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: high blood pressure, bone loss (osteoporosis), depression, diabetes, eye problems (such as cataracts, glaucoma), heart problems (such as angina, irregular heartbeat), any recent infection, liver problems, overactive thyroid (hyperthyroidism), seizures.

Fluticasone/vilanterol 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 fluticasone/vilanterol, 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 fluticasone/vilanterol safely.

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).

Fluticasone/vilanterol 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.

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. However, similar drugs pass 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.

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 heartbeat, shaking (tremor).

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (such as cortisol levels, lung function, eye exam, bone density tests) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

Avoid allergens/irritants such as smoke, pollen, pet dander, dust, or molds that may worsen asthma and other breathing problems.

Because the flu virus can worsen breathing problems, ask your doctor or pharmacist whether you should have an annual flu shot.

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.

STORAGE:

Different brands of this medication have different

storage needs. Check the product package for instructions on how to store your brand, or ask your pharmacist. Keep all medications

away from children and pets.

Do not remove the inhaler from its original foil package until ready to use. Discard the inhaler 6 weeks after you remove it from the original foil package or when the counter reads "0," whichever is sooner.

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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