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Wolters Kluwer

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Fluticasone and vilanterol: Patient drug information

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(For additional information [see "Fluticasone and vilanterol: Drug information"](#))

Brand Names: US

Breo Ellipta

Brand Names: Canada

Breo Ellipta

What is this drug used for?

- It is used to treat COPD (chronic obstructive pulmonary disease).
- It is used to treat asthma.
- This drug is not to be used to treat intense flare-ups of shortness of breath. Use a rescue inhaler. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

For all patients taking this drug:

- If you have an allergy to fluticasone, vilanterol, or any other part of this drug.
- If you have a milk allergy.

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.

Children:

- If the patient is a child. This drug is not approved for use in children.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all patients taking this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have high blood sugar (diabetes), this drug may sometimes raise blood sugar. Talk with your doctor about how to keep your blood sugar under control.
- Call your doctor right away if your breathing problems get worse, if your rescue inhaler does not work as well, or if you need to use your rescue inhaler more often.
- Do not take more of this drug or use it more often than you have been told. Deaths have happened when too much of this type of drug has been taken. Talk with your doctor.
- When changing from an oral steroid to another form of a steroid, there may be very bad and sometimes deadly side effects. Signs like weakness, feeling tired, dizziness, upset stomach, throwing up, not thinking clearly, or low blood sugar may happen. Call your doctor right away if you have any of these signs. If you have a bad injury, have surgery, or any type of infection, you may need extra doses of oral steroids. These extra steroids will help your body deal with these stresses. Carry a warning card saying that there may be times when you may need extra steroids.
- Long-term use may raise the chance of cataracts or glaucoma. Talk with the doctor.
- Have an eye exam as you have been told by your doctor.
- This drug may cause weak bones (osteoporosis) with long-term use. Talk with your doctor to see if you have a higher chance of weak bones or if you have any questions.

- Have a bone density test as you have been told by your doctor. Talk with your doctor.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Chickenpox and measles can be very bad or even deadly in some people taking steroid drugs like this drug. Avoid being near anyone with chickenpox or measles if you have not had these health problems before. If you have been exposed to chickenpox or measles, talk with your doctor.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

COPD:

- The chance of getting pneumonia is higher in people with COPD. This drug may raise the chance of getting pneumonia. The chance of having to go to the hospital for pneumonia may also be higher. Some cases have been deadly. Talk with the doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Signs of low potassium levels like muscle pain or weakness, muscle cramps, or a heartbeat that does not feel normal.
- Signs of a weak adrenal gland like a very bad upset stomach or throwing up, very bad dizziness or passing out, muscle weakness, feeling very tired, mood changes, not hungry,

or weight loss.

- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Chest pain or pressure or a fast heartbeat.
- Shakiness.
- Feeling nervous and excitable.
- Bone pain.
- Change in eyesight, eye pain, or very bad eye irritation.
- Mouth irritation or mouth sores.
- Redness or white patches in mouth or throat.
- Feeling very tired or weak.
- This drug can cause very bad breathing problems right after you take a dose. Sometimes, this may be life-threatening. If you have trouble breathing, breathing that is worse, wheezing, or coughing after using this drug, use a rescue inhaler and get medical help right away.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Runny nose.
- Nose or throat irritation.
- Signs of a common cold.
- Flu-like signs.
- Change in voice.
- Back pain.
- Joint pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- For breathing in only.
- Take this drug at the same time of day.
- Keep using this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Do not take out the inhaler from the foil tray until right before first use.
- Close the device after each dose. Do not open the device unless a dose is being used.
- Do not take the device apart or wash it. Do not use it with a spacer. Do not breathe out into the device.
- Rinse out mouth after each use. Do not swallow the rinse water. Spit it out.
- If you are using more than 1 inhaled drug, ask the doctor which drug to use first.

What do I do if I miss a dose?

- Use a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not use 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- Protect from heat and sunlight.
- Store in a dry place. Do not store in a bathroom.
- After opening, throw away any part not used after 6 weeks or when the indicator reads zero, whichever comes first.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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