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Fluticasone (oral inhalation): Patient drug information

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(For additional information <u>see "Fluticasone (oral inhalation): Drug information"</u> and <u>see "Fluticasone (oral inhalation): Pediatric drug information"</u>)

Brand Names: US

ArmonAir Digihaler; ArmonAir RespiClick 113 [DSC]; ArmonAir RespiClick 232 [DSC]; ArmonAir RespiClick 55 [DSC]; Arnuity Ellipta; Flovent Diskus; Flovent HFA

Brand Names: Canada

Aermony RespiClick; Arnuity Ellipta; Flovent Diskus; Flovent HFA; PMS-Fluticasone HFA

What is this drug used for?

- It is used to treat asthma.
- Do not use this drug to treat an asthma attack. Use a rescue inhaler. Talk with your doctor.

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

All products:

• 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 take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, or depression. There are many drugs that must not be taken with this drug. Your doctor or pharmacist can tell you if you are taking a drug that must not be taken with this drug.

All dry powder inhaler products:

• If you have a milk allergy.

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?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- 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.
- It may take a few weeks to see the full effect.
- If you have been taking this drug for many weeks, talk with your doctor before stopping. You may want to slowly stop this drug.
- 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.
- 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 your eye pressure checked if you are on this drug for a long time. Talk with 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.
- Use with care in children. Talk with the doctor.
- This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

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 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 Cushing's disease like weight gain in the upper back or belly, moon face, very bad headache, or slow healing.
- Feeling very tired, weak, or touchy; trembling; having a fast heartbeat, confusion, sweating, or dizziness if you missed a dose or recently stopped this drug.
- Flushing.
- Redness or white patches in mouth or throat.
- Bone or joint pain.

- Change in eyesight.
- Change in voice.
- Trouble speaking.
- 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:

- Signs of a common cold.
- Nose or throat irritation.
- Headache.
- Feeling tired or weak.
- Flu-like signs.
- Diarrhea, upset stomach, or throwing up.
- Muscle 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.

All products:

- Keep using this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Use this drug at the same time of day.
- For breathing in only.
- 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.

Inhaler (aerosol):

- Shake well before use.
- Prime before first use by shaking well for 5 seconds and then spraying into the air. Do this again 3 more times. If the inhaler has not been used for more than 7 days or is dropped, shake well for 5 seconds and then spray into the air 1 time.
- Do not get this drug in the eyes.
- Put the cap back on after you are done using your dose.
- A spacer may be used with the inhaler for easy use.
- Do not use near an open flame or while smoking. It may burst.

All dry powder inhaler products:

- Do not prepare a dose until you need to take it. If you prepare a dose and close the inhaler without taking a dose, it will waste the drug and may damage the inhaler.
- Do not breathe out into the inhaler. Close the inhaler after you use your dose.
- Do not take the device apart or wash it. Do not use it with a spacer. Do not breathe out into the device.
- Clean mouthpiece by wiping with a dry tissue or cloth. Do not wash or put in water.

Digital dry powder inhaler:

• This product keeps track of inhaler event information and may be used with a smartphone app. This product can be used without being connected to the smartphone app. Be sure you know how to use this product and the smartphone app. Follow what the doctor has told you to do. Read the package insert for details. If you have questions, talk with the doctor.

What do I do if I miss a dose?

- Skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

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

<u>All products:</u>

- Store at room temperature in a dry place. Do not store in a bathroom.
- Do not freeze.

- 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.

Inhaler (aerosol):

- Some inhalers have a dose counter to keep track of how many doses are left. If your inhaler has a dose counter, throw the inhaler away when the dose counter reaches "0."
- Protect from heat or open flame. Do not puncture or burn even if it seems empty.

All dry powder inhaler products:

- Store in foil until ready for use. Be sure you know how long this brand of this drug is good for after opening the foil. Throw away the inhaler after this amount of time or when the dose counter reaches "0", whichever comes first.
- Protect from heat and sunlight.
- Protect from cold.

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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