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## Fluticasone and Salmeterol Oral Inhalation

pronounced as (floo tik' a sone) (sal me' te role)

### Why is this medication prescribed?

The combination of fluticasone and salmeterol (Advair Diskus, Advair HFA, AirDuo Respiclick) is used to treat difficulty breathing, wheezing, shortness of breath, coughing, and chest tightness caused by asthma. The combination of fluticasone and salmeterol (Advair Diskus) is also used to prevent and treat wheezing, shortness of breath, coughing, and chest tightness caused by chronic obstructive pulmonary disease (COPD; a group of lung diseases that includes chronic bronchitis and emphysema). The combination of fluticasone and salmeterol (Advair Diskus) is used in adults and children 4 years of age and older. The combination of fluticasone and salmeterol (Advair HFA, AirDuo Respiclick) is used in children 12 years of age and older. Fluticasone is in a class of medications called steroids. It works by reducing swelling in the airways. Salmeterol is in a class of medications called long-acting beta-agonists (LABAs). It works by relaxing and opening air passages in the lungs, making it easier to breathe.

### How should this medicine be used?

The combination of fluticasone and salmeterol comes as a powder and as an inhalation solution to inhale by mouth using a specially designed inhaler. It is usually used twice a day, in the morning and evening, about 12 hours apart. Use fluticasone and salmeterol at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use fluticasone and salmeterol exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

Talk to your doctor about how you should take your other oral or inhaled medications for asthma during your treatment with salmeterol and fluticasone inhalation. If you were using a short-acting beta agonist inhaler such as albuterol (Proventil, Ventolin) on a regular basis, your doctor will probably tell you to stop using it regularly but to continue to use it to treat sudden attacks of asthma symptoms. Follow these directions carefully. Do not change the way you use any of your medications or stop taking any of your medications without talking to your doctor.

Do not use fluticasone and salmeterol during an attack of asthma or COPD. Your doctor will prescribe a short-acting inhaler to use during attacks.

Fluticasone and salmeterol inhalation controls the symptoms of certain lung diseases but does not cure these conditions. It may take a week or longer before you feel the full benefit of fluticasone and salmeterol. Continue to use fluticasone and salmeterol even if you feel well. Do not stop using fluticasone and salmeterol without talking to your doctor. If you stop using fluticasone and salmeterol inhalation, your symptoms may return.

Before you use fluticasone and salmeterol inhalation (Advair Diskus, Advair HFA, or AirDuo Resplick) for the first time, read the written package instructions that come with it. Look at the diagrams and package instructions carefully and be sure that you recognize all the parts of the inhaler. Ask your doctor, pharmacist, or respiratory therapist to show you how to use the inhaler. Practice using your inhaler while they watch, so you are sure you are doing it the right way.

If your child will be using fluticasone and salmeterol inhalation, be sure that he or she knows how to use it. Watch your child each time they use the inhaler to be sure that they are using it correctly.

Never exhale into the inhaler, take the inhaler apart, or wash the mouthpiece or any part of the inhaler. Keep the inhaler dry. Do not use the inhaler with a spacer.

Ask your pharmacist or doctor for a copy of the fluticasone and salmeterol inhalation (Advair Diskus, Advair HFA, or AirDuo Resplick) manufacturer's information for the patient.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before using fluticasone and salmeterol oral inhalation,

- tell your doctor and pharmacist if you are allergic to fluticasone (Flonase, Flovent), salmeterol (Serevent), any other medications, milk protein, any foods, or any of the ingredients in fluticasone and salmeterol oral inhalation. Ask your pharmacist or check the Patient Information for a list of the ingredients.
- tell your doctor if you use another LABA such as formoterol (Perforomist, in Dulera, in Symbicort) or salmeterol (Serevent, in Advair). These medications should not be used with fluticasone and salmeterol inhalation. Your doctor will tell you which medication you should use and which medication you should stop using.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention any of the following: certain antifungals such as itraconazole (Onmel, Sporanox) and ketoconazole; beta-blockers such as atenolol (Tenormin), labetalol (Trandate), metoprolol (Lopressor, Toprol XL), nadolol (Corgard), and propranolol (Inderal); clarithromycin (Biaxin, in Prevpac); diuretics ('water pills'); HIV protease inhibitors such as atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir), and saquinavir (Invirase); other medications for asthma or COPD; medications for seizures; metronidazole (Flagyl); nefazodone; and telithromycin (Ketek; no longer available in U.S.). Also tell your doctor and pharmacist if you are taking the following medications or have stopped taking them during the past 2 weeks: antidepressants such as amitriptyline, amoxapine, clomipramine (Anafranil), desipramine (Norpramin), doxepin (Silenor), imipramine (Tofranil), nortriptyline (Pamelor), protriptyline (Vivactil), and trimipramine (Surmontil); and monoamine oxidase (MAO)

inhibitors, including isocarboxazid (Marplan), linezolid (Zyvox), methylene blue, phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranylcypromine (Parnate). Many other medications may also interact with fluticasone and salmeterol, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you or anyone in your family has or has ever had osteoporosis (a condition in which the bones become weak and fragile), and if you have or have ever had high blood pressure, irregular heartbeat, seizures, hyperthyroidism (overactive thyroid), diabetes, tuberculosis (TB), cataracts (clouding of the lens of the eye), glaucoma (an eye disease), any condition that affects your immune system, or liver or heart disease. Also tell your doctor if you have a herpes eye infection or any other type of infection and if you smoke or use tobacco products.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while using fluticasone and salmeterol, call your doctor.
- if you are having surgery, including dental surgery, tell your doctor or dentist that you are using fluticasone and salmeterol.
- tell your doctor if you have never had chickenpox or measles and have not been vaccinated against these infections. Stay away from people who are sick, especially people who have chickenpox or measles. If you are exposed to these infections or if you develop symptoms of these infections, call your doctor immediately. You may need to get a vaccine (shot) to protect you from these infections.

## What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit or drinking grapefruit juice while taking this medication.

## What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not inhale a double dose to make up for a missed one.

## What side effects can this medication cause?

**Fluticasone and salmeterol may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- runny nose
- sneezing
- sore throat
- throat irritation
- sinus pain
- headache
- nausea
- vomiting
- diarrhea
- stomach pain

- muscle and bone pain
- dizziness
- weakness
- tiredness
- sweating
- tooth pain
- shaking of a part of your body that you cannot control
- sleep problems

**Some side effects can be serious. If you experience any of the following side effects, call your doctor immediately:**

- coughing, wheezing, or chest tightness that begins soon after you inhale fluticasone and salmeterol
- hives
- rash
- swelling of the face, throat, tongue, lips, hands, feet, ankles, or lower legs
- choking or difficulty swallowing
- hoarseness
- noisy, high-pitched breathing
- pounding fast, or irregular heartbeat
- fainting
- chest pain
- cough
- burning or tingling in the hands or feet
- white patches in the mouth
- fever, chills, and other signs of infection

Fluticasone and salmeterol may cause children to grow more slowly. Your child's doctor will monitor your child's growth carefully. Talk to your child's doctor about the risks of giving this medication to your child.

Fluticasone and salmeterol may increase the risk that you will develop glaucoma or cataracts. You will probably need to have regular eye exams during your treatment with fluticasone and salmeterol. Tell your doctor if you have any of the following: pain, redness, or discomfort of the eyes; blurred vision; seeing halos or bright colors around lights; or any other changes in vision. Talk to your doctor about the risks of using this medication.

Fluticasone and salmeterol may increase your risk of developing osteoporosis. Talk to your doctor about the risks of using this medication.

Fluticasone and salmeterol may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from sunlight, excess heat and moisture (not in the bathroom). Talk to your pharmacist about the proper disposal of your medication.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- seizures
- chest pain
- dizziness
- fainting
- blurred vision
- fast, pounding, or irregular heartbeat

- nervousness
- headache
- shaking of a part of your body that you cannot control
- muscle cramps or weakness
- dry mouth
- nausea
- excessive tiredness
- lack of energy
- difficulty falling asleep or staying asleep

## What other information should I know?

Keep all appointments with your doctor and your eye doctor.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Advair<sup>®</sup> Diskus
- Advair<sup>®</sup> HFA
- AirDuo<sup>®</sup> Respiclick

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

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