

## Fluticasone and Salmeterol Oral Inhalation

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

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### Important Warning:

In a large clinical study, more patients with asthma who used salmeterol experienced severe episodes of asthma that had to be treated in a hospital or caused death than patients with asthma who did not use salmeterol. If you have asthma, use of salmeterol may increase the risk that you will develop serious or fatal asthma problems. There is not enough information available to tell whether inhaling fluticasone with salmeterol increases, decreases, or does not change this risk.

Your doctor will only prescribe fluticasone and salmeterol if your asthma is so severe that two medications are needed to control it. You will never use salmeterol alone; you must always use it along with another asthma controller medication such as fluticasone. Children and teenagers who need to be treated with salmeterol will probably be treated with a combination product that combines salmeterol and another medication such as fluticasone in a single inhaler to make it easier for them to use both medications as prescribed.

Because of the risks of using salmeterol, you should only use fluticasone and salmeterol as long as both medications are needed to bring your asthma symptoms under control. Once your asthma is controlled, your doctor will probably tell you to stop using salmeterol but continue using fluticasone or another asthma medication. Your doctor will probably prescribe a different inhaler that contains only one medication to use instead of the fluticasone and salmeterol combination inhaler.

Do not use fluticasone and salmeterol if you have asthma that is quickly getting worse. Tell your doctor if you have had many severe asthma attacks or if you have ever been hospitalized because of asthma symptoms. If you have any of the following signs of worsening asthma, call your doctor immediately:

- your short-acting inhaler (inhaled medication such as albuterol [Proventil, Ventolin] that is used to treat sudden attacks of asthma symptoms) does not work as well as it did in the past
- you need to use more puffs than usual of your short-acting inhaler or use it more often
- you need to use four or more puffs per day of your short acting inhaler for 2 or more days in a row
- you use one whole canister (200 inhalations) of your short acting inhaler during an 8-week period
- your peak-flow meter (home device used to test breathing) results show that your breathing problems are worsening

- you need to go to the emergency room for asthma treatment
- your asthma symptoms do not improve after you use fluticasone and salmeterol inhalation regularly for 1 week or your symptoms get worse at any time during your treatment

Talk to your doctor about the risks of using this medication.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with fluticasone and salmeterol and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>) or the manufacturer's website to obtain the Medication Guide.

### Why is this medication prescribed?

The combination of fluticasone and salmeterol is used to prevent wheezing, shortness of breath, and breathing difficulties caused by asthma and chronic obstructive pulmonary disease (COPD; a group of lung diseases that includes chronic bronchitis and emphysema). 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 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 asthma and COPD 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 for the first time, ask your doctor, pharmacist, or respiratory therapist to show you how to use the inhaler. Practice using your inhaler while he or she watches.

To use the inhaler, follow these steps:

- If you will be using a new inhaler for the first time, remove it from the box and the foil wrapper. Fill in the blanks on the inhaler label with the date that you opened the pouch and the date 1 month later when you must replace the inhaler.
- Hold the inhaler in one hand, and put the thumb of your other hand on the thumbgrip. Push your thumb away from you as far as it will go until the mouthpiece appears and snaps into position.
- Hold the inhaler in a level, horizontal position with the mouthpiece toward you. Slide the lever away from you as far as it will go until it clicks.
- Every time the lever is pushed back, a dose is ready to inhale. You will see the number in the dose counter go down. Do not waste doses by closing or tilting the inhaler, playing with the lever, or advancing the lever more than once.
- Hold the inhaler level and away from your mouth, and breathe out as far as you comfortably can.
- Keep the inhaler in a level, flat position. Put the mouthpiece to your lips. Breathe in quickly and deeply through the inhaler, not through your nose.
- Remove the inhaler from your mouth, and hold your breath for 10 seconds or as long as you comfortably can. Breathe out slowly.
- You will probably taste or feel the salmeterol powder released by the inhaler. Even if you do not, do not inhale another dose. If you are not sure you are getting your dose of fluticasone and salmeterol, call your doctor or pharmacist.
- Rinse your mouth with water, but do not swallow.
- Put your thumb on the thumbgrip and slide it back toward you as far as it will go. The inhaler will click shut.

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.

## 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,

- tell your doctor and pharmacist if you are allergic to fluticasone (Flonase, Flovent), salmeterol (Serevent), any other medications, milk protein, or any foods.
- tell your doctor if you use another LABA such as formoterol (Foradil) or salmeterol (Serevent). 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: antifungals such as fluconazole (Diflucan), itraconazole (Sporanox), and ketoconazole (Nizoral); beta-blockers such as atenolol

(Tenormin), labetalol (Normodyne), metoprolol (Lopressor, Toprol XL), nadolol (Corgard), and propranolol (Inderal); cimetidine (Tagamet); clarithromycin (Biaxin); cyclosporine (Neoral, Sandimmune); danazol (Danocrine); delavirdine (Rescriptor); diltiazem (Cardizem, Dilacor, Tiazac); diuretics ('water pills'); fluoxetine (Prozac, Sarafem); fluvoxamine (Luvox); HIV protease inhibitors such as atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir), and saquinavir (Invirase); isoniazid (INH, Nydrazid); other medications for asthma or COPD; medications for seizures; metronidazole (Flagyl); nefazodone; oral contraceptives (birth control pills); telithromycin (Ketek); troleandomycin (TAO); verapamil (Calan, Covera, Isoptin, Verelan); and zafirlukast (Accolate). 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 (Elavil), amoxapine (Asendin), clomipramine (Anafranil), desipramine (Norpramin), doxepin (Adapin, Sinequan), imipramine (Tofranil), nortriptyline (Aventyl, Pamelor), protriptyline (Vivactil), and trimipramine (Surmontil); and monoamine oxidase (MAO) inhibitors, including isocarboxazid (Marplan), phenelzine (Nardil), selegiline (Eldepryl), and tranylcypromine (Parnate). 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), glaucoma (an eye disease), any condition that affects your immune system, liver disease, 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, if you do not eat a healthy diet, or if you do not exercise very often.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. 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
- red or dry eyes
- 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
- blurred vision
- 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, cataracts, or osteoporosis. You will probably need to have regular eye exams and bone tests during your treatment with fluticasone and salmeterol. 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 [at

<http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

## What storage conditions are needed for this medicine?

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). Throw away the inhaler 1 month after you remove it from the foil overwrap or after every blister has been used (when the dose indicator reads 0), whichever comes first. Talk to your pharmacist about the proper disposal of your medication.

## In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- 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.



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**The following brand names are from RxNorm,  
a standardized nomenclature for clinical  
drugs produced by the National Library of  
Medicine:**

### **Brand names**

- Advair 100/50
- Advair 115/21
- Advair 230/21
- Advair 250/50
- Advair 45/21
- Advair 500/50