

PATIENT INFORMATION

Fluticasone Propionate (floo tik' a sone proe' pee oh nate) and Salmeterol (sal mee' ter ol) Inhalation Powder, USP for oral inhalation use

What is fluticasone propionate and salmeterol inhalation powder?

- Fluticasone propionate and salmeterol inhalation powder combines the inhaled corticosteroid (ICS) medicine fluticasone propionate and the long-acting beta₂-adrenergic agonist (LABA) medicine salmeterol.
 - ICS medicines such as fluticasone propionate help to decrease inflammation in the lungs. Inflammation in the lungs can lead to breathing problems.
 - LABA medicines such as salmeterol help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.
- **Fluticasone propionate and salmeterol inhalation powder is not used to relieve sudden breathing problems** and will not replace a rescue inhaler.
- It is not known if fluticasone propionate and salmeterol inhalation powder is safe and effective in children younger than 4 years.
- Fluticasone propionate and salmeterol inhalation powder is used for asthma and COPD as follows:

Asthma:

- Fluticasone propionate and salmeterol inhalation powder is a prescription medicine used to control symptoms of asthma and to prevent symptoms such as wheezing in adults and children aged 4 years and older.
- Fluticasone propionate and salmeterol inhalation powder contains salmeterol, the same medicine found in SERVENT DISKUS. LABA medicines such as salmeterol when used alone increase the risk of hospitalizations and death from asthma problems. Fluticasone propionate and salmeterol inhalation powder contains an ICS and a LABA. When an ICS and LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.
- Fluticasone propionate and salmeterol inhalation powder is not for adults and children with asthma who are well controlled with an asthma control medicine, such as a low to medium dose of an ICS medicine. Fluticasone propionate and salmeterol inhalation powder is for adults and children with asthma who need both an ICS and LABA medicine.

COPD:

Fluticasone propionate and salmeterol inhalation powder 250 mcg/50 mcg is a prescription medicine used to treat COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. Fluticasone propionate and salmeterol inhalation powder 250 mcg/50 mcg is used long term as 1 inhalation 2 times each day to improve symptoms of COPD for better breathing and to reduce the number of flare-ups (the worsening of your COPD symptoms for several days).

Do not use fluticasone propionate and salmeterol inhalation powder:

- to relieve sudden breathing problems.
- as a rescue inhaler.
- if you have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- if you are allergic to fluticasone propionate, salmeterol, or any of the ingredients in fluticasone propionate and salmeterol inhalation powder. See the end of this Patient Information for a complete list of ingredients in fluticasone propionate and salmeterol inhalation powder.

Before using fluticasone propionate and salmeterol inhalation powder, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- have high blood pressure.
- have seizures.
- have thyroid problems.
- have diabetes.
- have liver problems.
- have weak bones (osteoporosis).
- have an immune system problem.
- have or have had eye problems such as glaucoma, increased pressure in your eye, cataracts, or other changes in vision.
- are allergic to milk proteins.
- have any type of viral, bacterial, or fungal infection.
- are exposed to chickenpox or measles.
- are pregnant or plan to become pregnant. It is not known if fluticasone propionate and salmeterol inhalation powder may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in fluticasone propionate and salmeterol inhalation powder pass into your milk and if they can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Fluticasone propionate and salmeterol inhalation powder and certain other medicines may interact with each other. This may cause serious side effects. Especially tell your healthcare provider if you take antifungal or anti-HIV medicines.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use fluticasone propionate and salmeterol inhalation powder?

Read the step-by-step instructions for using fluticasone propionate and salmeterol inhalation powder at the end of this Patient Information.

- **Do not** use fluticasone propionate and salmeterol inhalation powder unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
- Children should use fluticasone propionate and salmeterol inhalation powder with an adult's help, as instructed by the child's healthcare provider.
- Fluticasone propionate and salmeterol inhalation powder comes in 2 different strengths. Your healthcare provider prescribed the strength that is best for you.
- Use fluticasone propionate and salmeterol inhalation powder exactly as your healthcare provider tells you to use it. **Do not** use fluticasone propionate and salmeterol inhalation powder more often than prescribed.
- Use 1 inhalation of fluticasone propionate and salmeterol inhalation powder 2 times each day. Use fluticasone propionate and salmeterol inhalation powder at the same time each day, about 12 hours apart.
- If you miss a dose of fluticasone propionate and salmeterol inhalation powder, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at 1 time.
- If you take too much fluticasone propionate and salmeterol inhalation powder, call your healthcare provider or go to the nearest hospital emergency room right away if you have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness.
- **Do not use other medicines that contain a LABA for any reason.** Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.
- **Do not** stop using fluticasone propionate and salmeterol inhalation powder, even if you are feeling better, unless your healthcare provider tells you to.
- **Fluticasone propionate and salmeterol inhalation powder does not relieve sudden breathing problems.** Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.
- Rinse your mouth with water **without swallowing** after each dose of fluticasone propionate and salmeterol inhalation powder. This will help lessen the chance of getting a yeast infection (thrush) in your mouth and throat.
- Call your healthcare provider or get medical care right away if:
 - your breathing problems get worse.
 - you need to use your rescue inhaler more often than usual.
 - your rescue inhaler does not work as well to relieve your symptoms.
 - you need to use 4 or more inhalations of your rescue inhaler in 24 hours for 2 or more days in a row.
 - you use 1 whole canister of your rescue inhaler in 8 weeks.
 - your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.
 - you have asthma and your symptoms do not improve after using fluticasone propionate and salmeterol inhalation powder regularly for 1 week.

What are the possible side effects of fluticasone propionate and salmeterol inhalation powder?

Fluticasone propionate and salmeterol inhalation powder can cause serious side effects, including:

- **fungal infection in your mouth or throat (thrush).** Rinse your mouth with water **without swallowing** after using fluticasone propionate and salmeterol inhalation powder to help reduce your chance of getting thrush.
- **pneumonia.** People with COPD have a higher chance of getting pneumonia. Fluticasone propionate and salmeterol inhalation powder may increase the chance of you getting pneumonia. Call your healthcare provider right away if you have any of the following symptoms:
 - increase in mucus (sputum) production
 - change in mucus color
 - fever
 - chills
 - increased cough
 - increased breathing problems
- **weakened immune system and increased chance of getting infections (immunosuppression).**
- **reduced adrenal function (adrenal insufficiency).** Adrenal insufficiency is a condition where the adrenal glands do not make enough steroid hormones. This can happen when you stop taking oral corticosteroid medicines (such as prednisone) and start taking a medicine containing an inhaled steroid (such as fluticasone propionate and salmeterol inhalation powder). During this transition period, when your body is under stress such as from fever, trauma (such as a car accident), infection, surgery, or worse COPD symptoms, adrenal insufficiency can get worse and may cause death.
Symptoms of adrenal insufficiency include:
 - feeling tired
 - lack of energy
 - weakness
 - nausea and vomiting
 - low blood pressure (hypotension)
- **sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop using fluticasone propionate and salmeterol inhalation powder and call your healthcare provider right away.
- **serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following symptoms of a serious allergic reaction:
 - rash
 - hives
 - swelling of your face, mouth, and tongue
 - breathing problems
- **effects on heart.**
 - increased blood pressure
 - a fast or irregular heartbeat
 - chest pain
- **effects on nervous system.**
 - tremor
 - nervousness
- **bone thinning or weakness (osteoporosis).**

- **slowed growth in children.** Your child's growth should be checked regularly by the healthcare provider while using fluticasone propionate and salmeterol inhalation powder.
- **eye problems** including glaucoma, increased pressure in your eye, cataracts, or other changes in vision. You should have regular eye exams while using fluticasone propionate and salmeterol inhalation powder.
- **changes in laboratory blood levels (sugar, potassium, certain types of white blood cells).** **Common side effects of fluticasone propionate and salmeterol inhalation powder include:**

Asthma:

- | | |
|--|-----------------------|
| • upper respiratory tract infection | • bronchitis |
| • throat irritation | • cough |
| • hoarseness and voice changes | • headache |
| • thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this. | • nausea and vomiting |

In children with asthma, infections in the ear, nose, and throat are common.

COPD:

- | | |
|--|--------------------------------|
| • thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this. | • viral respiratory infections |
| • throat irritation | • headache |
| • hoarseness and voice changes | • muscle and bone pain |

These are not all the possible side effects of fluticasone propionate and salmeterol inhalation powder.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store fluticasone propionate and salmeterol inhalation powder?

- Store fluticasone propionate and salmeterol inhalation powder at room temperature between 68°F and 77°F (20°C and 25°C). Keep in a dry place away from heat and sunlight.
- Store fluticasone propionate and salmeterol inhalation powder in the unopened foil pouch and only open when ready for use.
- Safely throw away fluticasone propionate and salmeterol inhalation powder in the trash 1 month after you open the foil pouch or when the counter reads 0, whichever comes first.

Keep fluticasone propionate and salmeterol inhalation powder and all medicines out of the reach of children.

General information about the safe and effective use of fluticasone propionate and salmeterol inhalation powder.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use fluticasone propionate and salmeterol inhalation powder for a condition for which it was not prescribed. Do not give fluticasone propionate and salmeterol inhalation powder to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about fluticasone propionate and salmeterol inhalation powder that was written for health professionals.

What are the ingredients in fluticasone propionate and salmeterol inhalation powder?

Active ingredients: fluticasone propionate, salmeterol xinafoate

Inactive ingredient: lactose monohydrate (contains milk proteins)

For more information about fluticasone propionate and salmeterol inhalation powder, call 1-844-834-0530 or visit our website at www.lannett.com.

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INSTRUCTIONS FOR USE
Fluticasone Propionate (floo tik' a sone proe' pee oh nate) and
Salmeterol (sal mee' ter ol) Inhalation Powder, USP
for oral inhalation use

Read this Instructions for Use before you start using fluticasone propionate and salmeterol inhalation powder and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Your fluticasone propionate and salmeterol inhalation powder inhaler



Figure A

Important information about your fluticasone propionate and salmeterol inhalation powder inhaler:

- **Fluticasone propionate and salmeterol inhalation powder is for oral inhalation use only.**
- Take fluticasone propionate and salmeterol inhalation powder out of the foil pouch just before you use it for the first time. Safely throw away the pouch. The inhaler will be in the closed position.
- Write the date you opened the foil pouch in the first blank line on the label. **See Figure A.**
- Write the "use by" date in the second blank line on the label. **See Figure A.** That date is 1 month after the date you wrote in the first line.
- The counter should read **60**.

How to use your fluticasone propionate and salmeterol inhalation powder inhaler

Follow these steps every time you use fluticasone propionate and salmeterol inhalation powder.

Step 1. Open your fluticasone propionate and salmeterol inhalation powder inhaler.

- Hold the inhaler in your left hand and place the thumb of your right hand in the thumb grip. Push the thumb grip away from you as far as it will go until the mouthpiece shows and snaps into place. **See Figure B.**

Step 2. Slide the lever until you hear it click.

- **Hold the inhaler in a level, flat position** with the mouthpiece towards you. Slide the lever away from the mouthpiece as far as it will go until it **clicks**. **See Figure C.**



Figure B

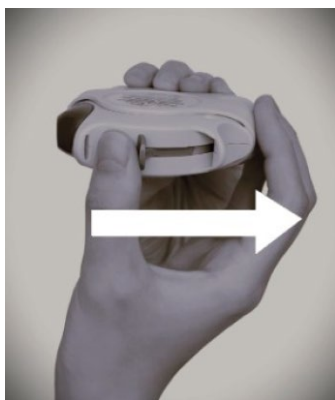


Figure C

- The number on the counter will count down by 1. The inhaler is now ready to use.

Follow the instructions below so you will not accidentally waste a dose:

- **Do not** close the inhaler.
- **Do not** tilt the inhaler.
- **Do not** move the lever on the inhaler.

Step 3. Inhale your medicine.

- Before you breathe in your dose from the inhaler, breathe out (exhale) as long as you can while you hold the inhaler level and away from your mouth. **See Figure D.** Do not breathe into the mouthpiece.
- Put the mouthpiece to your lips. **See Figure E.** Breathe in quickly and deeply through the inhaler.

Do not breathe in through your nose.



Figure D



Figure E

- Remove the inhaler from your mouth **and hold your breath for about 10 seconds**, or for as long as is comfortable for you.
- **Breathe out slowly as long as you can.** **See Figure D.**
- The inhaler delivers your dose of medicine as a very fine powder that you may or may not taste or feel. **Do not** take an extra dose from the inhaler even if you do not taste or feel the medicine.

Step 4. Close the inhaler.

- Place your thumb in the thumb grip and slide it back towards you as far as it will go. **See Figure F.** Make sure the inhaler clicks shut and you cannot see the mouthpiece.



Figure F

- The inhaler is now ready for you to take your next scheduled dose in about 12 hours. **When you are ready to take your next dose, repeat Steps 1 through 4.**

Step 5. Rinse your mouth.

- Rinse your mouth with water after breathing in the medicine.** Spit out the water. Do not swallow it. **See Figure G.**



Figure G

When should you get a refill?

The counter on top of the inhaler shows you how many doses are left. After you have taken **55** doses, the numbers **5** to **0** will show in red. **See Figure H.** These numbers warn you there are only a few doses left and are a reminder to get a refill.



Figure H

For correct use of the inhaler, remember:

- Always use the inhaler in a level, flat position.
- Make sure the lever firmly clicks into place.
- Hold your breath for about 10 seconds after inhaling. Then breathe out fully.
- After each dose, rinse your mouth with water and spit it out. Do not swallow the water.
- **Do not** take an extra dose, even if you did not taste or feel the powder.
- **Do not** take the inhaler apart.
- **Do not** wash the inhaler.
- Always keep the inhaler in a dry place.
- **Do not** use the inhaler with a spacer device.

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