

# SERETIDE EVOHALER DOSE COUNTER

Salmeterol xinafoate/ Fluticasone propionate (25/50 mcg, 25/125 mcg, 25/250 mcg)

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## What SERETIDE is used for

Your doctor has chosen this medicine to suit you and your condition. SERETIDE is used to help with breathing problems in people who need regular treatment.

Asthma is a long-term condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Chronic obstructive pulmonary disease (COPD) is a long-term, progressively worsening condition affecting the lungs, resulting from chronic bronchitis or emphysema. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up mucus. The primary cause of COPD symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

## How SERETIDE works

Salmeterol xinafoate is one of a group of medicines called

bronchodilators. It relaxes the muscles in the walls of the small air passages in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. The effects of salmeterol xinafoate last for at least 12 hours. When it is taken regularly it helps the small air passages to remain open.

Fluticasone propionate is one of a group of medicines called corticosteroids which are often referred to simply as steroids. Corticosteroids are used to treat breathing problems because they have an anti-inflammatory action. They reduce the swelling and irritation in the walls of the small air passages in the lungs and so ease breathing problems. Corticosteroids also help to prevent attacks of asthma. Fluticasone propionate should not be confused with other steroids such as anabolic steroids misused by some athletes and taken as tablets or injection.

When you take these two ingredients together regularly they will both help to control your breathing difficulties.

## Before you use SERETIDE

- When you must not use it  
DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help you. You will need a different type of medicine, which you must not confuse with SERETIDE. You should always have your fast-acting 'rescue' medicine available.

- Before you start to use it  
If you answer "Yes" to any of the following questions tell your doctor about this before taking your medicine.

- Are you pregnant or likely to become pregnant soon?

- Are you breast-feeding?
- Have you been told that you are allergic to SEREVENT or salmeterol xinafoate?
- Have you been told that you are allergic to FLIXOTIDE or fluticasone propionate?
- Have you ever had thrush in your mouth?
- Are you being or have you ever been treated for tuberculosis (TB)?
- Are you having treatment for a thyroid condition?
- Are you having treatment for high blood pressure or a heart problem?
- Are you taking a medicine called ketoconazole, used to treat fungal infections?

- Taking other medicines

In some cases, SERETIDE may not be suitable to use with other medicines (e.g. some HIV medicines). **You must not take SERETIDE if you are receiving a medicine called ritonavir, without first consulting your doctor.** Make sure your doctor knows what other medicines you are taking, including those that you have bought yourself.

## How to use SERETIDE

- How much to use

The medicine in the SERETIDE EVOHALER should be inhaled into your lungs. SERETIDE must only be breathed in through the mouth. If you have any difficulties or do not understand the instructions ask your doctor or pharmacist. Take your medicine as your doctor has told you. The label on it will usually tell you how much to take and how often. If you are not sure ask your doctor or pharmacist. The usual dose is:

## ASTHMA

- Adults and adolescents 12 years and older

Two puffs (25 micrograms salmeterol and 50 micrograms fluticasone propionate) twice daily.

Or

Two puffs (25 micrograms salmeterol and 125 micrograms fluticasone propionate) twice daily.

Or

Two puffs (25 micrograms salmeterol and 250 micrograms fluticasone propionate) twice daily.

- Children 4 years and older  
Two puffs (25 micrograms salmeterol and 50 micrograms fluticasone propionate) twice daily.

SERETIDE is not suitable for use by children under 4 years.

### **COPD**

- Adults

The maximum recommended dose is two puffs (25 micrograms salmeterol and 250 micrograms fluticasone propionate) twice daily.

### **Instructions for use**

#### *Testing your inhaler*

Before using for the first time, remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, hold the inhaler between fingers and thumb with your thumb at the base, below the mouthpiece and release puffs into the air until the counter reads 120 to make sure that it works. The inhaler should be shaken immediately before releasing each puff. If your inhaler has not been used for a week or more remove the mouthpiece cover, shake the inhaler well and release one puff into the air. Each time the inhaler is activated the number on the counter will count down by one. In certain circumstances,

dropping the inhaler may cause the counter to count on.

#### *Using your inhaler*

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.
2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.
3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the inhaler upright between the fingers and thumb with your thumb on the base, below the mouthpiece.
5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it, but do not bite it.
6. Just after starting to breathe in through your mouth, press firmly down on the top of the inhaler to release salmeterol and fluticasone propionate, while still breathing in steadily and deeply.
7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.
8. To take a second inhalation keep the inhaler upright and wait about half a minute before repeating steps 3 to 7.
9. Afterwards, rinse your mouth with water and spit it out.
10. Immediately replace the mouthpiece cover in the correct position. The cap when correctly fitted will click into position. If it does not click into place, turn the cap the other way round and try again. Do not use excessive force.

Do not rush stages 5, 6 and 7. It is important that you start to breathe in as slowly as possible just before operating your inhaler. Practise in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth you should start again from stage 2. You should consider getting a replacement when the counter shows the number 020. When the counter reads 000 you must replace it. Any puffs left in the device may not be enough to give you a full dose. Never try to alter the numbers on the counter or detach the counter from the metal canister. The counter cannot be reset and is permanently attached to the canister. If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties.

#### *Children*

Young children may need help and an adult may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practice the technique together. Older children or people with weak hands should hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the base below the mouthpiece.

#### *Cleaning*

Your inhaler should be cleaned at least once a week.

1. Remove the mouth piece cover.
2. Do not remove the canister from the plastic casing.
3. Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.

### **IMPORTANT**

4. Replace the mouthpiece cover in the correct position. The cap when correctly fitted will click into position. If it does not click into place, turn the cap the other way round and try again. Do not use excessive force.

**DO NOT PUT THE METAL CANISTER INTO WATER.**

**- When to use it**

It is very important that you use it regularly every day. Do not stop treatment even if you feel better unless told to do so by your doctor. Do not change your dose unless told to by your doctor. If you are breathless or wheezing more often than normal, tell your doctor.

**- How long to use it**

It is very important that you take your SERETIDE every day as directed. Keep taking it until your doctor tells you to stop.

**- If you forget to use it**

If you miss a dose just take the next dose when it is due.

**- If you use too much (overdose)**

If you accidentally take a larger dose than recommended you may notice that your heart is beating faster than usual and that you feel shaky. Other symptoms you may experience include headache, muscle weakness and aching joints. Tell your doctor as soon as possible if you accidentally take a larger dose than you were told to.

**While you are using it**

**- Things you must do**

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

**- Things you must not do**

This medicine is for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

**- Things to be careful of**

If you are breathless or wheezing more often than normal, tell your doctor.

**Side Effects**

Any medicine which contains corticosteroids may have some effect on patients. This is far more common when patients are taking oral corticosteroids. These effects are not usually seen with inhaled corticosteroids, but can occur in patients taking high doses for a long time. It is possible that these patients may experience: loss of bone density, eye problems, slowing of growth in children. Consult your doctor if you are worried about yourself or your children.

Most people taking this medicine find that it causes no problems. As with all medicines, a few people may find that it causes side effects. Some people can be allergic to medicines. If you have any of the following symptoms soon after taking SERETIDE, STOP taking this medicine and tell your doctor immediately.

- Sudden wheeziness and chest pain or tightness
- Swelling of eyelids, face, lips, tongue or throat
- Lumpy skin rash or “hives” anywhere on the body

Some people very occasionally find that their mouth, throat or tongue becomes sore or that their voice becomes hoarse after inhaling this medicine. Rinsing with water and spitting it out immediately after each dose may help. Tell your doctor but do not stop treatment unless told to do so. Also tell your doctor if you

have any of the following symptoms: headache, muscle cramps, pains in joints, skin rash or trembling, increase in pulse rate. Pneumonia (lung infection) has been reported commonly in patients with COPD. It is possible that some patients, particularly those taking higher doses of this type of medication, may very rarely suffer from the following side effects: Rounded face, loss of bone density, eye problems and slowing of growth in children. Some patients may experience increased bruising. There may be an increase in the amount of sugar (glucose) in your blood. If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required. Very rarely the person taking the medicine may feel anxious, have disturbed sleep or notice increase irritability (mainly in children). If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

**Pneumonia (infection of the lungs) in COPD patients (common side effect)**

Tell your doctor if you have any of the following while taking SERETIDE – they could be symptoms of a lung infection:

- Fever or chills;
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))].

**Storage and Disposal of SERETIDE**

- Storage

Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force. Keep your SERETIDE inhaler away from direct heat or sunlight. Also keep your inhaler away from frost, which may make your medicine work less well. The container contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn the inhaler even when it is empty. Do not use after the date shown as 'Exp' on the carton and label. Do not store above 30°C. Keep you inhaler where children cannot reach it. It may harm them.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

SERETIDE contains a suspension of salmeterol and fluticasone propionate in CFC-free propellant, HFA 134a. The medicine is contained in a pressurized can, with a mouthpiece and an 'actuator'. The can has a counter attached to show you how many puffs of medicine you have left. The number will show through a window in the back of the plastic actuator. Each time the can is pressed a puff of the medicine is released and the counter will count down by one. Each can contains 120 puffs of the medicine. Each puff contains 25 micrograms salmeterol and 50, 125 or 250 micrograms fluticasone propionate.

- Ingredients

- Active ingredient(s)  
25 micrograms salmeterol (as salmeterol xinafoate) and 50, 125 or 250 micrograms fluticasone propionate.

- Inactive ingredient(s)  
Norflurane (HFA 134a)

MAL number

SERETIDE Evohaler Dose Counter 25/50 MCG:

- MAL11040017ARZ

SERETIDE Evohaler Dose Counter 25/125 MCG:

- MAL11040018ARZ

SERETIDE Evohaler Dose Counter 25/250 MCG:

- MAL11040019ARZ

**Manufacturer**

Glaxo Wellcome S.A.  
Avenida de Extremadura 3,  
09400 Aranda de Duero,  
Burgos, Spain

**Product Registration Holder**

GlaxoSmithKline  
Pharmaceutical Sdn. Bhd.  
HZ.01, Horizon Penthouse,  
1 Powerhouse,  
1, Persiaran Bandar Utama,  
Bandar Utama,  
47800 Petaling Jaya  
Selangor, Malaysia

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