

SERETIDE ACCUHALER

Salmeterol xinafoate/ Fluticasone propionate (50/100, 50/250, 50/500 micrograms)

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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 (linings of the air sacs in the lungs damaged beyond repair). 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). SERETIDE Accuhaler, at a dose of 50/500 micrograms,

has been shown to increase survival and reduce the number of flare ups of COPD symptoms.

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.

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 been told you are allergic to lactose or milk proteins?
- 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 having treatment for diabetes mellitus?

- Taking other medicines

In some cases, SERETIDE may not be suitable to use with other medicines (e.g. some HIV medicines and ketoconazole, used to treat fungal infections).

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 Accuhaler should be inhaled into your lungs. You may not be able to taste or feel the powder on your tongue, even if you have used the Accuhaler correctly. The instructions for using the Accuhaler are given on the other side of this leaflet. If you have any difficulties or do not understand the instructions

ask your doctor or pharmacist. SERETIDE Accuhaler must only be breathed in through the mouth.

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

One puff (50 micrograms salmeterol and 100 micrograms fluticasone propionate) twice daily.

Or

One puff (50 micrograms salmeterol and 250 micrograms fluticasone propionate) twice daily.

Or

One puff (50 micrograms salmeterol and 500 micrograms fluticasone propionate) twice daily.

- Children 4 years and older

One puff (50 micrograms salmeterol and 100 micrograms fluticasone propionate) twice daily.

COPD

- Adults

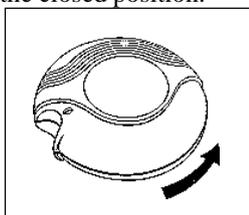
Maximum dose is one puff (50 micrograms salmeterol and 500 micrograms fluticasone propionate) twice daily.

Instructions for use

The Accuhaler is sealed in a foil overwrap. The overwrap provides moisture protection and should only be opened when you are ready to use it for the first time. Once opened the foil overwrap should be discarded. The Accuhaler releases a powder which is inhaled into the lungs. A dose indicator on the Accuhaler indicates the number of doses left.

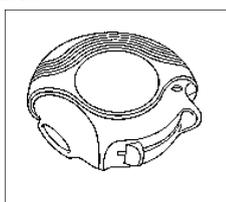
Closed

When you take your Accuhaler out of its box and remove any foil overwrap that may be present, the Accuhaler, will be in the closed position.



Opened

A new Accuhaler contains 28 or 60 doses individually protected doses of your medicine, in powder form. The dose indicator tells you how many doses are left.



Each dose is accurately measured and hygienically protected. It requires no maintenance - and no refilling. The dose indicator on top of your Accuhaler tells you how many doses are left. Numbers 5 to 0 will appear in RED, to warn you when there are only a few doses left. The Accuhaler is easy to use. When you need a dose, just follow the five simple steps illustrated:-

1. Open
2. Slide
3. Inhale
4. Close
5. Rinse

How your Accuhaler works

Sliding the lever of your Accuhaler opens a small hole in the mouthpiece and unwraps a dose, ready for you to inhale it. When you close the Accuhaler, the lever automatically moves back to its original position,

ready for your next dose when you need it. The outer case protects your Accuhaler when it is not in use.

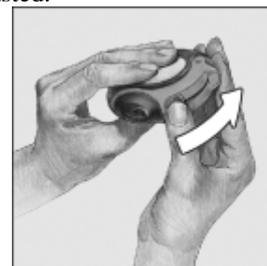
1. Open – How to use the Accuhaler

To open your Accuhaler, hold the outer case 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.



2. Slide

Hold your Accuhaler with the mouthpiece towards you. Slide the lever away from you, as far as it will go - until it clicks. Your Accuhaler is now ready to use. Every time the lever is pushed back, a dose is made available for inhaling. This is shown by the dose counter. Do not play with the lever as this releases doses which will be wasted.



3. Inhale

Before you start to inhale the dose, read through this section carefully. Hold the Accuhaler away from your mouth. Breathe out as far as is comfortable. Remember - never breathe into your Accuhaler. Put the mouthpiece to your lips. Breathe in steadily and deeply - through

the Accuhaler, not through your nose. Remove the Accuhaler from your mouth. Hold your breath for about 10 seconds, or for as long as it is comfortable. Breathe out slowly. You may not be able to taste or feel the powder on your tongue, even if you have used the Accuhaler correctly.



4. Close

To close your Accuhaler, put your thumb in the thumbgrip, and slide the thumbgrip back towards you, as far as it will go. When you close the Accuhaler, it clicks shut. The lever automatically returns to its original position and is reset. Your Accuhaler is now ready for you to use again.



5. Rinse

Afterwards, rinse your mouth with water and spit it out. If you have been instructed to take two inhalations you must close the Accuhaler and repeat stages 1 to 4.

REMEMBER

Keep your Accuhaler dry. Keep it closed when not in use. Never breathe into your Accuhaler. Only slide the lever when you are ready to take a dose. Do not exceed the stated dose. Keep out of reach of children.

- When to use it

It is very important that you use your SERETIDE Accuhaler every day, as instructed by your doctor. This will help you to keep free of symptoms throughout the day and night.

- 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 even if you have no symptoms.

- If you forget to use it

Take your next dose when it is due. Do not take a double dose to replace the one you forgot.

- 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, low potassium level (muscle weakness). 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 may develop hoarseness, difficulty swallowing or thrush (candidiasis) in their mouth or throat and, rarely in their oesophagus. 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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SERETIDE

- *Storage*

Keep your SERETIDE Accuhaler away from direct heat

or sunlight. Keep your Accuhaler in a dry place. Store the Accuhaler in the foil overwrap until you are ready to use it for the first time. Once opened the foil overwrap should be discarded. Do not store above 30°C. Do not use after the date shown as 'Exp' on the carton and label. Keep your Accuhaler 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 Accuhaler is a moulded plastic device containing a foil strip with 28 or 60 blisters. Each blister contains 50 micrograms of the active ingredient salmeterol xinafoate. Each blister also contains 100 or 250 or 500 micrograms of the active ingredient fluticasone propionate, the amount depends on which strength of SERETIDE you have been given. Each blister also contains lactose as a carrier. The blisters protect the powder for inhalation from the effects of the atmosphere. The Accuhaler device has a dose counter which tells you the number of doses remaining. It counts down from 28 or 60 to 1. The numbers appear in red when the last five doses have been reached.

- *Ingredients*

• Active ingredient(s)
50 micrograms salmeterol xinafoate and 10, 250 or 500 micrograms fluticasone propionate.

• Inactive ingredient
Lactose monohydrate (which contains milk protein), see *Before you use SERETIDE*.

- *MAL numbers*

- SERETIDE Accuhaler 50/100 MCG:
 - MAL20001531ARZ
- SERETIDE Accuhaler 50/250 MCG:
 - MAL20001532ARZ
- SERETIDE Accuhaler 50/500 MCG:
 - MAL20001533ARZ

Manufacturer

Glaxo Wellcome Production
Zone Industrielle No. 2
23, rue Lavoisier
27000 Evreux
France

Product Registration Holder

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

Selangor, Malaysia

Date of Revision

09/03/2023

Serial Number

NPRA (R1/5) 06122022/323