

SERETIDE

Fluticasone propionate/Salmeterol xinafoate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using SERETIDE.

This leaflet answers some common questions about SERETIDE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SERETIDE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SERETIDE is used for

SERETIDE is available as a dry powder device called an ACCUHALER and a Metered Dose Inhaler (MDI) also known as an "inhaler".

- SERETIDE ACCUHALER: 100/50, 250/50, 500/50
- SERETIDE MDI: 50/25, 125/25, 250/25

SERETIDE is used to help with asthma and chronic obstructive pulmonary disease (COPD) in people who need regular treatment.

Asthma is a 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 condition affecting the lungs, resulting from chronic bronchitis or emphysema. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up phlegm. The COPD symptoms are mainly due to bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

SERETIDE contains two medicines, fluticasone propionate and salmeterol xinafoate.

Fluticasone propionate belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are the steroids sometimes misused by athletes.

Corticosteroids have an anti-inflammatory action. They reduce the swelling and irritation in the walls of the small air passages in the lungs and so help you to breathe more easily. Corticosteroids are used to treat asthma and COPD.

Salmeterol xinafoate is a bronchodilator. A bronchodilator keeps the breathing tubes in your lungs open and relieves the symptoms of asthma and other chest conditions. The effects of salmeterol xinafoate last for up to twelve hours.

When taken together regularly fluticasone propionate and salmeterol help to control your breathing difficulties.

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, e.g. VENTOLIN (salbutamol), which you must not confuse with SERETIDE.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive. This medicine is available only with a doctor's prescription.

Before you use SERETIDE

When you must not take it

Do not take SERETIDE if you have an allergy to:

- any medicine containing fluticasone propionate
- any medicine containing salmeterol xinafoate
- lactose monohydrate or milk proteins (this applies to ACCUHALER only)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- wheezing or difficulty breathing
- swelling of the face, eyelids, lips/mouth, tongue or throat
- chest pain or tightness
- hay fever or lumpy rash ("hives")
- fainting

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you use it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- thrush in your mouth
- tuberculosis
- diabetes
- a thyroid condition
- high blood pressure or a heart problem
- low blood potassium levels

Tell your doctor if you are taking other steroid medicines by mouth or inhalation

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking SERETIDE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SERETIDE may interfere with each other. These include:

- Beta-blockers used to treat high blood pressure (hypertension)
- Ketoconazole used to treat fungal infection

- Ritonavir used to treat HIV infection

These medicines may be affected by SERETIDE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

How to take SERETIDE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

It is very important that you use the medicine 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.

ACCUHALER

ASTHMA

Adults and adolescents 12 years and older:

Your doctor will prescribe 1 of 3 different strengths of SERETIDE ACCUHALER for you, depending on the severity of your condition:

- SERETIDE ACCUHALER 100/50 (100 micrograms of

fluticasone propionate and 50 micrograms of salmeterol), or

- SERETIDE ACCUHALER 250/50 (250 micrograms of fluticasone propionate and 50 micrograms of salmeterol), or
- SERETIDE ACCUHALER 500/50 (500 micrograms of fluticasone propionate and 50 micrograms of salmeterol).

The usual dose is one puff from your ACCUHALER twice a day.

Children 4 years and older:

The usual dose is one puff from your SERETIDE ACCUHALER 100/50 (100 micrograms of fluticasone propionate and 50 micrograms of salmeterol) twice a day.

No information is available on use of SERETIDE ACCUHALER in children under 4 years old.

COPD

Adults:

Your doctor will prescribe 1 of 2 different strengths of SERETIDE ACCUHALER for you:

- SERETIDE ACCUHALER 250/50 (250 micrograms of fluticasone propionate and 50 micrograms of salmeterol), or
- SERETIDE ACCUHALER 500/50 (500 micrograms of fluticasone propionate and 50 micrograms of salmeterol).

The usual dose is one puff from your ACCUHALER twice a day.

MDI

ASTHMA

Adults and adolescents 12 years and older:

Your doctor will prescribe 1 of 3 different strengths of SERETIDE MDI for you, depending on the severity of your condition:

- SERETIDE MDI 50/25 (50 micrograms of fluticasone propionate and 25 micrograms of salmeterol), or
- SERETIDE MDI 125/25 (125 micrograms of fluticasone

propionate and 25 micrograms of salmeterol), or

- SERETIDE MDI 250/25 (250 micrograms of fluticasone propionate and 25 micrograms of salmeterol).

The usual dose is two puffs from your inhaler twice a day.

Children 4 years and older:

The usual dose is two puffs from your SERETIDE MDI 50/25 (50 micrograms of fluticasone propionate and 25 micrograms of salmeterol) twice a day.

No information is available on use of SERETIDE MDI in children under 4 years old.

COPD

Adults:

Your doctor will prescribe 1 of 2 different strengths of SERETIDE MDI for you:

- SERETIDE MDI 125/25 (125 micrograms of fluticasone propionate and 25 micrograms of salmeterol), or
- SERETIDE MDI 250/25 (250 micrograms of fluticasone propionate and 25 micrograms of salmeterol).

The usual dose is two puffs from your inhaler twice a day.

How to take it

The medicine in SERETIDE should be inhaled into your lungs.

SERETIDE must only be breathed in through the mouth.

The full instructions for using SERETIDE are given on a leaflet inside the pack.

If you have any difficulties or do not understand the instructions, ask your doctor or pharmacist.

If you find it difficult to use your SERETIDE MDI, talk to your doctor or pharmacist. It may be better for you to use something called a spacer device. Your doctor or pharmacist will explain what this is and how to use it.

If you change the make of spacer you use this may alter the amount of drug delivered to the lungs. You should let your doctor know if your asthma symptoms worsen.

ACCUHALER

Your SERETIDE ACCUHALER is hygienically protected. It requires no maintenance and no refilling.

MDI

If your SERETIDE MDI is new and you have not used it before, you should release puffs into the air until the counter reads 120 to make sure that it works.

If your SERETIDE MDI has not been used for one week or more, you should release two puffs into the air before use.

Each time a puff is released the number on the counter will count down by one.

In some cases dropping the inhaler may cause the counter to count down.

Cleaning: Your Inhaler should be cleaned at least once a week as follows:

1. Remove the mouthpiece 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.
4. Replace the mouthpiece cover.

DO NOT PUT THE METAL CANISTER INTO WATER.

Use your medicine as your doctor has told you. If you are not sure ask your doctor or pharmacist.

When to take it

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

It is very important that you use your SERETIDE every day, twice a day. This will help you to keep free

of symptoms throughout the day and night.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, then go back to using it as you would normally.

Do not use a double dose to make up for the dose that you missed.

If you become wheezy or feel tight in the chest before the next dose is due, use a 'reliever puffer' in the usual way. You should get relief from your 'reliever puffer' within a few minutes.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 13 11 26 and in New Zealand telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SERETIDE.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

Symptoms of an overdose may include:

- rapid heart beat
- increased rate of breathing
- significant muscle tremor
- headache
- increased blood pressure
- increased blood sugar (glucose) levels

If you are not sure what to do, contact your doctor or pharmacist.

While you are using SERETIDE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SERETIDE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

It is important that all doctors treating you are aware that you are on inhaled steroids. If your body is stressed by, for example, severe infection, surgical operation, an accident etc, you may need steroid tablets or injections for a time.

If you become pregnant while taking this medicine, or are trying to become pregnant, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Contact your doctor if you experience a change in your vision.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take SERETIDE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you, or their symptoms seem similar to yours.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

This medicine is not expected to affect your ability to drive a car or operate machinery. It is prudent to be careful driving or operating machinery until you know how SERETIDE affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SERETIDE, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

If your breathing or wheezing gets worse straight after using your ACCUHALER or MDI, stop using it immediately and tell your doctor as soon as possible.

This medicine helps most people with asthma and COPD. Most people using this medicine find that it causes no problem, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Common Side Effects

- soreness in the mouth, throat, or tongue
- hoarseness
- headache
- muscle cramps
- pains in joints
- increase in heart rate

Pneumonia (lung infection) has been reported commonly in patients with COPD.

Uncommon Side Effects

- skin rash
- shortness of breath
- sweating, trembling, feeling nervous or anxious
- bruising
- Eye problems (e.g. cataract, glaucoma)
- sleep disturbances

Rare Side Effects

- swelling of the face, lips, mouth, tongue or throat
- irregular heartbeat
- behavioural changes, including unusual activity and irritability (mainly in children).
- Rounded face
- Slowing of growth in children and adolescents
- Soreness in the oesophagus

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital, as you may be having an allergic reaction:

- wheezing or difficulty breathing
- swelling of the face, eyelids, lips/mouth, tongue or throat
- chest pain or tightness
- hay fever or lumpy rash ("hives")
- fainting

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Some side effects, for example changes in blood sugar (glucose) level, blood pressure or loss of bone density can only be found when your doctor does tests from time to time to check your progress.

Taking high doses of steroids for a long time could affect the adrenal glands, which make the body's own steroid. Your doctor may do tests to check how the adrenal glands are working.

Your doctor will be able to answer any questions you may have.

If you have any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

After using SERETIDE

Rinse mouth after use

Some people find that their mouth, throat or tongue becomes sore or that their voice becomes hoarse after inhaling this medicine. It may be helpful to rinse your mouth with water and spit it out after using your SERETIDE. Tell your doctor but do not stop treatment unless told to do so.

Storage

Keep your SERETIDE in a dry place where the temperature

stays below 30°C, away from direct heat or sunlight.

Do not store SERETIDE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

If your SERETIDE MDI becomes very cold, it may not work properly. Keep your Inhaler away from frost.

WARNING: The SERETIDE MDI metal can is pressurised. Do not burn it or puncture it, even when it is empty. Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ACCUHALER

SERETIDE ACCUHALER is a moulded plastic inhaler device containing a foil strip with 28 or 60 blisters.

Each blister 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 50 micrograms of the active ingredient salmeterol.

Each different strength of SERETIDE is represented by a different shade of purple on the carton and ACCUHALER labels.

Each blister also contains lactose monohydrate 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 0. The numbers appear in red when the last five doses have been reached.

Never use your ACCUHALER if the dose counter reads 0. When the counter shows 0 your ACCUHALER is empty and should be disposed of.

MDI

SERETIDE MDI consists of a plastic casing which contains a small metal canister. The casing has a mouthpiece which is covered by a cap.

Each canister contains 28 or 120 doses of the medicine.

Each dose contains 50 or 125 or 250 micrograms of the active ingredient fluticasone propionate.

Each dose also contains 25 micrograms of active ingredient salmeterol. The amount depends on which strength of SERETIDE you have been given.

The canister has a counter attached to show how many puffs of medicine you have left. The number of puffs left will show through a window in the back of the plastic casing. Each time the canister is pressed a dose of the medicine is released and the counter will count down by one.

You should consider getting a replacement when the counter shows the number 020.

Do not use your SERETIDE MDI if the counter shows 000. When the counter shows 000 you must dispose of your SERETIDE MDI.

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.

Ingredients

SERETIDE contains the active ingredients:

- fluticasone propionate
- salmeterol xinafoate

Your SERETIDE ACCUHALER also contains lactose monohydrate (which contains milk protein)

Your SERETIDE MDI also contains HFA-134a, a CFC-Free propellant.

Supplier

SERETIDE is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford Victoria 3067
Australia.

SERETIDE is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland 1143
New Zealand

SERETIDE ACCUHALER

- 100/50 - AUST R 70089
- 250/50 - AUST R 70091
- 500/50 - AUST R 70174

SERETIDE MDI

- 50/25 - AUST R 120661
- 125/25 - AUST R 120662
- 250/25 - AUST R 120663

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