

# SERETIDE

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using SERETIDE?

SERETIDE contains the active ingredients fluticasone propionate and salmeterol xinafoate. SERETIDE is used to help with asthma and chronic obstructive pulmonary disease (COPD) in people who need regular treatment. For more information, see Section [1. Why am I using SERETIDE?](#) in the full CMI.

### 2. What should I know before I use SERETIDE?

Do not use if you have ever had an allergic reaction to any medicine containing fluticasone propionate or salmeterol xinafoate or lactose monohydrate or milk proteins (this applies to ACCUHALER only) or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use SERETIDE?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with SERETIDE and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use SERETIDE?**

- Follow dosage directions given to you by your doctor or pharmacist and continue taking it for as long as your doctor tells you.
- SERETIDE should be inhaled into your lungs through the mouth, through one of two presentations; the ACCUHALER or the Metered Dose Inhaler (MDI).

More instructions can be found in Section [4. How do I use SERETIDE?](#) in the full CMI.

### **5. What should I know while using SERETIDE?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul>
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	<p>you visit that you are using SERETIDE.</p> <ul style="list-style-type: none"> <li>● If you are going to have surgery, tell the surgeon or anesthesiologist that you are taking this medicine.</li> <li>● Tell your doctor if you become, or are trying to become, pregnant.</li> <li>● Tell your doctor if you are using SERETIDE, if you have any blood tests.</li> <li>● Contact your doctor if you experience a change in your vision.</li> <li>● Keep all of your doctor's appointments so that your progress can be checked.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine suddenly or change the dosage without checking with your doctor.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● 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</li> </ul>

	<p>machinery until you know how SERETIDE affects you.</p>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• Keep SERETIDE in a dry place where the temperature stays below 30°C away from direct heat or sunlight.</li> <li>• The SERETIDE MDI metal canister is pressurised. Do not burn it or puncture it, even when empty. Keep it where children cannot reach it.</li> </ul>

For more information, see Section [5. What should I know while using SERETIDE?](#) in the full CMI.

## 6. Are there any side effects?

The following common side effects may occur when taking SERETIDE; soreness in the mouth, throat or tongue, hoarseness, headache, muscle cramps, pain in joints, increase in heart rate, pneumonia. If your breathing or wheezing gets worse straight after using SERETIDE, stop using it immediately and tell your doctor as soon as possible.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.



# SERETIDE

**Active ingredients:** Fluticasone propionate/Salmeterol xinafoate

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using SERETIDE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SERETIDE.**

**Where to find information in this leaflet:**

- [1. Why am I using SERETIDE?](#)
- [2. What should I know before I use SERETIDE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SERETIDE?](#)
- [5. What should I know while using SERETIDE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using SERETIDE?

**SERETIDE contains the active ingredients 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.

**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).

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.

**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

## **2. What should I know before I use SERETIDE?**

### **Warnings**

#### **Do not use SERETIDE if:**

- you are allergic to fluticasone propionate or salmeterol xinafoate, lactose monohydrate or milk proteins (this applies to ACCUHALER only) or any of the ingredients listed at the end of this leaflet. 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 or fainting.
- always check the ingredients to make sure you can use this medicine.
- the expiry date (EXP) printed on the pack has passed or if the packaging is torn and shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

#### **Check with your doctor if you:**

- have any allergies to any other medicines, foods, preservatives or dyes.
- have any other medical conditions, including thrush in your mouth, tuberculosis, diabetes, a thyroid condition, high blood pressure or a heart problem, low blood potassium levels.

- are taking other steroid medicines by mouth or inhalation.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

## **3. What if I am taking other medicines?**

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

**Some medicines may interfere with SERETIDE and affect how it works.**

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SERETIDE.**

## **4. How do I use 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.

Follow the instructions provided and use SERETIDE until your doctor tells you to stop.

## **When to take SERETIDE**

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(s) 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.

**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.

## **How to take SERETIDE**

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.**

## **After using SERETIDE**

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.

## **If you forget to use SERETIDE**

SERETIDE should be used regularly at the same time each day. If you miss your dose at the usual time, **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 use too much SERETIDE**

If you think that you have used too much SERETIDE, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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.

## **5. What should I know while using SERETIDE?**

### **Things you should 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.

- **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.

## **Call your doctor straight away if you:**

- Think you may be having an allergic reaction
- Experience a change in your vision
- Notice any symptoms listed in section 6

## **Things you should 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.

## **Driving or using machines**

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.

## Looking after your medicine

- **Keep your SERETIDE in a dry place where the temperature stays below 30°C, away from direct heat or sunlight.**
- If your SERETIDE MDI becomes very cold, it may not work properly. Keep your Inhaler away from frost.
- **WARNING: The SERETIDE MDI metal canister is pressurised. Do not expose to temperatures higher than 50°C. Do not burn it or puncture it, even when it is empty.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- **Keep it where children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**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.**

### Less serious side effects

Less serious side effects	What to do
<p><b>Mouth/throat:</b></p> <ul style="list-style-type: none"><li>• hoarseness</li><li>• soreness of mouth, throat or tongue</li><li>• soreness in the oesophagus</li></ul> <p><b>Cardiovascular:</b></p> <ul style="list-style-type: none"><li>• increased blood pressure</li><li>• increase in heart rate</li></ul> <p><b>Pain:</b></p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● headache</li> <li>● muscle cramps</li> <li>● pains in joints</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>● skin rash</li> <li>● bruises</li> </ul> <p><b>Anxiety and behavioural changes:</b></p> <ul style="list-style-type: none"> <li>● sweating, trembling, feeling nervous or anxious</li> <li>● sleep disturbances</li> <li>● unusual activity and irritability (mainly in children)</li> </ul> <ul style="list-style-type: none"> <li>● <b>Other:</b></li> <li>● slowing of growth in children and adolescents</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Allergic Reaction:</b></p> <ul style="list-style-type: none"><li>• wheezing or difficulty breathing</li><li>• swelling of the face, eyelids, lips/mouth, tongue or throat</li><li>• chest pain or tightness</li><li>• hay fever or lumpy rash ("hives")</li><li>• fainting</li></ul> <p><b>Respiratory:</b></p> <ul style="list-style-type: none"><li>• pneumonia (lung infection)</li><li>• shortness of breath</li></ul> <p><b>Cardiovascular:</b></p> <ul style="list-style-type: none"><li>• irregular heartbeat</li></ul> <p><b>Ocular:</b></p> <ul style="list-style-type: none"><li>• eye problems (e.g. cataract, glaucoma)</li></ul> <p><b>Other:</b></p> <ul style="list-style-type: none"><li>• rounded face</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

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.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What SERETIDE contains

<b>Active ingredient (main ingredient)</b>	fluticasone propionate salmeterol xinafoate
<b>Other ingredients (inactive ingredients)</b>	<b>ACCUHALER</b> lactose monohydrate (which contains milk protein)  <b>MDI</b> HFA-134a, a CFC-Free propellant

**Do not take this medicine if you are allergic to any of these ingredients.**

### What SERETIDE 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.

## **Who distributes SERETIDE**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford Victoria 3067

Australia.

### **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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