

SERETIDE[®] ACCUHALER[®]

Fluticasone propionate/Salmeterol xinafoate

Consumer Medicine Information

Patient's Name
First Address Line
Second Address Line

What is in this leaflet?

Please read this leaflet carefully before you use Seretide Accuhaler.

This leaflet answers some common questions about Seretide Accuhaler. It does not contain all of 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 using Seretide Accuhaler against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Seretide Accuhaler is used for

Seretide Accuhaler 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 Accuhaler 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 known as 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.

Your doctor may have prescribed Seretide Accuhaler for another reason.

Ask your doctor if you have any questions about why Seretide Accuhaler has been prescribed for you.

The medicine in Seretide Accuhaler is not addictive.

Before you use Seretide Accuhaler

When you must not use it

- **Do not use Seretide Accuhaler if you have ever had an allergic reaction to fluticasone propionate (Flixotide), salmeterol xinafoate (Serevent), lactose or milk protein.**

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the

following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

- **Do not use Seretide Accuhaler if you are pregnant, trying to become pregnant or breast-feeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using Seretide Accuhaler if you are pregnant or breast-feeding.

- **Do not use Seretide Accuhaler after the expiry date (EXP) printed on the pack.**

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

- **Do not use Seretide Accuhaler if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be using Seretide Accuhaler, talk to your doctor.

Before you start to use it

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines**
- **you are pregnant or likely to become pregnant**
- **you are breast-feeding**
- **you have ever had thrush in your mouth**

- **you are being or have ever been treated for tuberculosis (TB)**
- **you are having treatment for a thyroid condition**
- **you are having treatment for high blood pressure or a heart problem**

Using other medicines

Tell your doctor if you are using any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. For example, a class of medicines known as "beta-blockers" used to treat hypertension should be avoided. Other medicines like ketoconazole, used to treat fungal infection, and ritonavir used to treat HIV infection, may also affect how Seretide Accuhaler works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

How to use Seretide Accuhaler

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.

How much to use

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 mcg fluticasone propionate and 50 mcg salmeterol) or
- Seretide Accuhaler 250/50 (250 mcg fluticasone propionate and 50 mcg salmeterol) or
- Seretide Accuhaler 500/50 (500 mcg fluticasone propionate and 50 mcg 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 mcg fluticasone propionate and 50 mcg 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 mcg fluticasone propionate and 50 mcg salmeterol) or
- Seretide Accuhaler 500/50 (500 mcg fluticasone propionate and 50 mcg salmeterol)

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

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.

How to use it

The medicine in the Seretide Accuhaler should be inhaled into your lungs.

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

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

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.

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

When to use it

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

It is very important that you use your Seretide Accuhaler every day, twice a day. This will help you to keep free of symptoms throughout the day and night.

Seretide Accuhaler should not be used to relieve a sudden attack of breathlessness or wheezing.

If you get this sort of attack you must use a quick-acting inhaler (e.g. Ventolin).

If you feel you are getting breathless or wheezy more often than normal, or you are using your quick-acting inhaler more than usual, you should go to your doctor.

If you forget to use 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 use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have used too much Seretide, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are using Seretide Accuhaler

Things you must do

Tell your doctor or pharmacist that you are using Seretide Accuhaler if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

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 stop using Seretide, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Seretide Accuhaler to treat any other complaints unless your doctor says to.

Do not use Seretide Accuhaler after the expiry date shown on the carton and label.

Things to be careful of

Be careful driving or operating machinery until you know how Seretide Accuhaler affects you.

Seretide Accuhaler generally does not cause any problems with your ability to drive a car

or operate machinery. However, as with many other medicines, Seretide Accuhaler may cause dizziness/drowsiness/tiredness in some people.

Side-Effects

Check with your doctor as soon as possible if you have any problems while using Seretide Accuhaler, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Most people using this medicine find that it causes no problem. Like other medicines, Seretide Accuhaler can cause some side-effects. If side effects occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- soreness of the throat or tongue
- hoarseness
- headache
- muscle cramps
- pains in joints
- skin rash or trembling
- increase in heart rate

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

It is possible that some people, particularly those taking higher doses of Seretide Accuhaler for a long time, may rarely suffer from the following side effects:

- rounded face
- loss of bone density
- eye problems (eg. cataract, glaucoma)

- slowing of growth in children. It is unclear what, if any, difference this makes to a child's final height.

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.

It is important that:

- treatment with your Seretide Accuhaler is not stopped suddenly.
- 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.

Very rarely the person taking the medicine may feel anxious, have disturbed sleep or notice increased irritability (mainly in children).

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

If you think you are having an allergic reaction to Seretide Accuhaler, STOP using this medicine and TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms of an allergic reaction usually include some or all of the following:

- wheezing
- swelling of the lips, mouth, tongue or throat

- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After using Seretide Accuhaler

Rinse mouth after use

Some people find that their 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 Accuhaler. Tell your doctor but do not stop treatment unless told to do so.

Storage

Keep this medicine where young children cannot reach it.

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

Keep Seretide Accuhaler in a dry place where it stays

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

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using Seretide Accuhaler, or the Seretide Accuhaler has passed its expiry date, ask your pharmacist what to do with any Seretide Accuhaler left over.

Product description

What Seretide Accuhaler looks like

Seretide Accuhaler is a moulded plastic inhaler device containing a foil strip with 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. The Accuhaler for all 3 Seretide strengths is a combination of purple and mauve.

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 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.

Ingredients

Seretide Accuhaler contains the active ingredients fluticasone propionate and salmeterol xinafoate.

It also contains lactose (which contains milk protein).

It does not contain gluten or sucrose.

Manufacturer

Your Seretide Accuhaler is supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia Victoria 3155

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 28 March 2007.

The information provided applies only to: **Seretide® Accuhaler®**.

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AUST R 70091
Seretide Accuhaler 500/50:
AUST R 70174

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