

Seretide™

Salmeterol Xinafoate /Fluticasone Propionate

Salmeterol xinafoate equivalent to 25 micrograms of salmeterol and 50, 125 or 250mcg of fluticasone propionate (Inhaler) and salmeterol xinafoate 50mcg and fluticasone propionate 100mcg, 250mcg or 500mcg (Accuhaler).

Consumer Medicine Information Leaflet

Please read this leaflet carefully before you start taking Seretide

What you should know about Seretide

This leaflet talks only about Seretide. Please read it carefully before you start to use your medicine. It tells you the main points about the medicine. For more information or advice ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has outweighed the risks of you using Seretide against the benefits this medicine is expected to have for you.

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

Keep the leaflet with the medicine. You may want to read it again.

The name of your medicine

The name of your medicine is salmeterol xinafoate/fluticasone propionate (Seretide). Seretide is available in a dry powder device called an Accuhaler and in a Metered Dose Inhaler. The inhaler is also known as a puffer.

What is in your medicine

Seretide inhaler contains a suspension of salmeterol xinafoate and fluticasone propionate in CFC-free propellant, HFA 134a. The medicine is contained in a pressurised can, with a mouthpiece and an 'actuator'. Each time the actuator is pressed a dose of the medicine is released. Each can contains 120 doses of the medicine. Each dose contains 25 micrograms (mcg) salmeterol (as xinafoate) and 50, 125 or 250 mcg fluticasone propionate.

Seretide Accuhaler is a purple coloured plastic device which contains a foil strip inside. The foil strip has 60 blisters (or pockets) which contain your medicine. Each blister contains 50 micrograms of salmeterol xinafoate and 100, 250 or 500mcg fluticasone propionate. Each blister also contains lactose powder (a milk protein).

How your medicine 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. 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.

What is Seretide 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.

It is very important that you use your Seretide every day, as instructed by your doctor. This will help you to keep free of symptoms

throughout the day and night.

Seretide 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 (eg. Ventolin™) also known as a reliever puffer.

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

Before you use Seretide

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 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 ritonavir, a medicine used in the treatment of HIV (AIDS)?

Make sure your doctor knows what other medicines you are taking, including those that you have bought yourself from a pharmacy, supermarket or health food shop.

When you must not use Seretide

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

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

How to use Seretide

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

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

- Seretide 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.

How much Seretide do I use?

Seretide Inhaler:

ASTHMA

Adults and adolescents 12 years and older:

Two inhalations of 25mcg salmeterol and 50mcg fluticasone propionate twice daily.

or

Two inhalations of 25mcg salmeterol and 125mcg fluticasone propionate twice daily.

or

Two inhalations of 25mcg salmeterol and 250mcg fluticasone propionate twice daily.

Children 4 years and older:

Two inhalations of 25mcg salmeterol and 50mcg fluticasone propionate twice daily.

COPD

Adults:

As directed by your doctor.

The maximum recommended dose is Two inhalations of 25mcg salmeterol and 250mcg fluticasone propionate twice daily.

Seretide Accuhaler:

ASTHMA

Adults and adolescents 12 years and older.

One inhalation of 50mcg salmeterol and 100mcg fluticasone propionate twice daily.

or

One inhalation of 50mcg salmeterol and 250mcg fluticasone propionate twice daily.

or

One inhalation of 50mcg salmeterol and 500mcg fluticasone propionate twice daily.

Children 4 years and older:-

One inhalation of 50mcg salmeterol and 100mcg fluticasone propionate twice daily.

Seretide is not suitable for use by children aged under 4 years.

COPD

Adults:

As directed by your doctor.

The maximum recommended dose is One inhalation of 50mcg salmeterol and 500mcg fluticasone propionate twice daily.

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.

Your doctor will decide what dose you should take, how often you should take it, and what strength of Seretide you should use. Do not change your dose unless told to by your doctor

You should visit your doctor or pharmacist regularly to check that you are using Seretide in the right way. If you are not breathing the medicine in correctly, the medicine may

not be helping you as much as it could.

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

What to do if you take too much (Overdose)

If you accidentally take a larger dose than recommended, your heart may beat faster than usual, you may get a headache, you may experience muscle weakness and aching joints or you may feel shaky and tense.

Tell your doctor as soon as possible if you accidentally take a larger dose than you were told to.

Immediately telephone your doctor or Poisons Information Centre for advice (0800 POISON or 0800 764 766), if you think you may have taken too much of your medicine, 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.

What to do if you miss a dose

You **must** use your Seretide every day. Do not stop using it, even if you feel better, unless your doctor tells you. If you forget to take a dose, do not worry. Just take the next dose when it is due.

Do not take 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.

While you are using Seretide

Things you must do

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

If you have to go into hospital for an operation, take your Seretide with you and tell the doctor what medicine(s) you are taking.

All doctors treating you need to be 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.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that your medicine was not effective and change your treatment unnecessarily.

If your breathing or wheezing gets worse straight after using Seretide, stop using it immediately

and tell your doctor as soon as possible.

Side-Effects

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 or lips
- 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. Gargling 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, skin rash or trembling, increase in pulse rate or irregular heartbeat.

A commonly reported side effect in patients with COPD is pneumonia (lung infection).

It is possible that in 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.
- An increase in sugar (glucose) in the blood.

Consult your doctor if you are worried about yourself or your children.

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

If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

After using Seretide

Storage

- Keep Seretide away from direct heat or sunlight.
- Also keep Seretide away from frost, which may make your medicine work less well.
- 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.
- Do not leave it in the car or on windowsills.

Disposal

If your doctor tells you to stop using Seretide or the product has passed its

expiry date, ask your pharmacist what to do with any Seretide left over.

Manufacturer

Seretide is supplied by:

GlaxoSmithKline NZ Ltd
Quay Tower
Cnr Albert and Customs St
Private Bag 106600
Downtown Auckland
New Zealand

Ph: (09) 367 2900

Fax (09) 367 2910

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.

The information provided applies to: Seretide™ and Ventolin™ inhaler are a trademark of the GlaxoSmithKline Group of Companies.

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