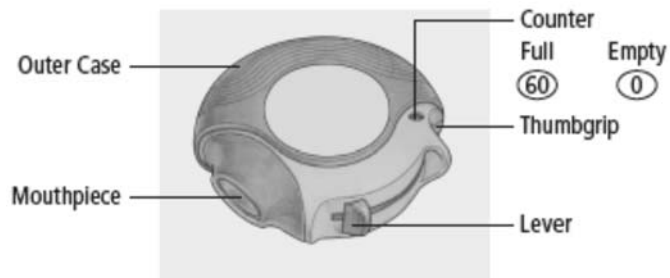


Package leaflet: Information for the user
Seretide® 250 Accuhaler®
(salmeterol xinafoate/fluticasone propionate)

Your medicine is known as the above but will be referred to as Seretide throughout the remainder of this leaflet.

Seretide is available in multiple strengths and all strengths will be referred to throughout the remainder of this leaflet.



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms and signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Seretide is and what it is used for
2. What you need to know before you use Seretide
3. How to use Seretide
4. Possible side effects
5. How to store Seretide
6. Contents of the pack and other information

1. What Seretide is and what it is used for

Seretide contains two medicines, salmeterol and fluticasone propionate:

- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

The doctor has prescribed this medicine to help prevent breathing problems such as:

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD). Seretide Accuhaler, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

You must use Seretide every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

Seretide helps to stop breathlessness and wheeziness coming on. However Seretide should not be used to relieve a sudden attack of breathlessness or wheezing. If this happens you need to use a fast-acting 'reliever' ('rescue') inhaler, such as salbutamol. You should always have your fast-acting 'rescue' inhaler with you.

2. What you need to know before you use Seretide

Do not take Seretide:

If you are allergic to salmeterol, fluticasone propionate or to the other ingredient lactose monohydrate.

Warnings and precautions

Talk to your doctor before using Seretide if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Seretide may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now or in the past, or other lung infections

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Seretide

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines including medicines for asthma or any medicines obtained without a prescription. This is because Seretide may not be suitable to be taken with some other medicines.

Tell your doctor if you are taking the following medicines, before starting to use Seretide:

- β blockers (such as atenolol, propranolol and sotalol). β blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ketoconazole, itraconazole and erythromycin) including some medicines for HIV treatment (such as ritonavir, cobicistat containing products). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase your risk of experiencing side effects with Seretide, including irregular heart beats, or may make side effects worse. Your doctor may wish to monitor you carefully if you are taking these medicines.
- Corticosteroids (by mouth or by injection). If you have had these medicines recently, this might increase the risk of this medicine affecting your adrenal gland.
- Diuretics, also known as 'water tablets' used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).
- Xanthine medicines. These are often used to treat asthma.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Seretide is not likely to affect your ability to drive or use machines.

Seretide Accuhaler contains lactose

Seretide Accuhaler contains up to 12.5 milligrams of lactose monohydrate in each dose. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose monohydrate contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use Seretide

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Use your Seretide every day until your doctor advises you to stop. Do not take more than the recommended dose. Check with your doctor or pharmacist if you are not sure.
- Do not stop taking Seretide or reduce the dose of Seretide without talking to your doctor first.
- Seretide should be inhaled through the mouth into the lungs.
- You may not be able to taste or feel the powder on your tongue, even if you have used the Accuhaler correctly.

For asthma

Adults and adolescents aged 12 years and over

- Seretide Accuhaler 50/100 - One inhalation twice a day
- Seretide Accuhaler 50/250 - One inhalation twice a day
- Seretide Accuhaler 50/500 - One inhalation twice a day

Children 4 to 12 years of age

- Seretide Accuhaler 50/100 - One inhalation twice a day
- Seretide is not recommended for use in children below 4 years of age.

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- Seretide Accuhaler 50/500 - One inhalation twice a day

Your symptoms may become well controlled using Seretide twice a day. If so, your doctor may decide to reduce your dose to once a day. The dose may change to:

- once at night - if you have **night-time** symptoms
- once in the morning - if you have **daytime** symptoms.

It is very important to follow your doctor's instructions on how many inhalations to take and how often to take your medicine.

If you are using Seretide for asthma, your doctor will want to regularly check your symptoms.

If your asthma or breathing gets worse tell your doctor straight away. You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. If any of these happen, you should continue to take Seretide but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

Instructions for use

- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the Seretide Accuhaler properly or as prescribed may mean that it will not help your asthma or COPD as it should.
- The Accuhaler device holds blisters containing Seretide as a powder.
- There is a counter on top of the Accuhaler which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty.

Using your inhaler

- 1** 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. You will hear a click. This will open a small hole in the mouthpiece.



- 2** Hold your Accuhaler with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece.



Every time the lever is pulled back a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.

- 3** Hold the Accuhaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your Accuhaler.

- 4** 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 is comfortable. Breathe out slowly.



- 5** Afterwards, rinse your mouth with water and spit it out, and/or brush your teeth. This may help to stop you getting thrush and becoming hoarse.

- 6** To close the Accuhaler, slide the thumbgrip back towards you, as far as it will go. You will hear a click. The lever will return to its original position and is reset.

