

PACKAGE LEAFLET: INFORMATION FOR THE USER
Seretide® 250 Evohaler® 25 microgram/250 microgram/dose
pressurised inhalation, suspension
salmeterol/fluticasone propionate

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others.
- It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Seretide is and what it is used for
2. Before you use Seretide
3. How to use Seretide
4. Possible side effects
5. How to store Seretide
6. Further 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.

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

Seretide helps to stop breathlessness and wheeziness coming on. It does not work once you are breathless or wheezy. If that happens you need to use a fast acting ‘reliever’ medication, such as salbutamol.

2. BEFORE YOU USE SERETIDE

Do not take Seretide if:

You are allergic (hypersensitive) to salmeterol, fluticasone propionate or to the other ingredient norflurane (HFA 134a).

Take special care with Seretide

Your doctor will supervise your treatment more closely if you have medical conditions such as:

- 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

If you have ever had any of these conditions, tell your doctor before you use Seretide.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes 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:

- Beta-blockers (such as atenolol, propranolol, sotalol). Beta-blockers are mostly used for high blood pressure or other heart conditions.
- Antiviral and antifungal medicines (such as ritonavir, ketoconazole and itraconazole). 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.
- 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.

Pregnancy and breast-feeding

If you are pregnant, planning to get pregnant, or breast feeding, talk to your doctor before taking Seretide. Your doctor will assess whether you can take Seretide during this time.

Driving and using machines

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

3. HOW TO USE SERETIDE

- Use your Seretide every day, until your doctor advises you to stop.
- Always use Seretide exactly as your doctor has told you. Don't exceed the recommended dose. Check with your doctor or pharmacist if you're not sure.

Adults and adolescents aged 12 years and over

- Seretide 25/50 Evohaler - 2 puffs twice a day
- Seretide 25/125 Evohaler - 2 puffs twice a day
- Seretide 25/250 Evohaler - 2 puffs twice a day

Children 4 to 12 years of age

- Seretide 25/50 Evohaler - 2 puffs twice a day
- Seretide is not recommended for use in children below 4 years of age.

Your symptoms may become well controlled using Seretide twice a day. If so, your doctor may decide to reduce your dose to once daily. 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 Evohaler properly or as prescribed may mean that it will not help your asthma as it should.
- The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.
- There is a counter on the back of the Evohaler which tells you how many doses are left. Each time you press the canister, a puff of medicine is released and the counter will count down by one.
- Take care not to drop the inhaler as this may cause the counter to count down.

Testing the inhaler

1. When using your inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.



2. To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release a puff into the air.

Repeat these steps, shaking the inhaler before releasing each puff, until the counter reads 120. If you have not used your inhaler for a week or more, release two puffs of medicine into the air.

Use of the inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1. Stand or sit upright when using your inhaler.



2. Remove the mouthpiece cover (as shown in first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.



3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable.

5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



6. Breathe in through your mouth. Just after starting to breathe in, press firmly down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.

7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.

8. Wait about half a minute between taking each puff of medicine and then repeat steps 3 to 7.

9. Afterwards, rinse your mouth with water and spit it out. This may help to stop you getting thrush and being hoarse.

10. After use always replace the mouthpiece cover straight away to keep out dust. When the mouthpiece cover is fitted correctly it will ‘click’ into position. If it does not ‘click’ into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.

If you or your child find it difficult to use the inhaler, either the Volumatic or Aerochamber Plus spacer device may be used. Before starting to use a spacer device for the first time or if you need to change your make of spacer device, talk to your doctor, nurse or pharmacist.

You should get a replacement when the counter shows the number 020. Stop using the inhaler when the counter shows 000 as any puffs left in the device may not be enough to give you a full dose. Never try to alter the numbers on the counter or detach the counter from the metal can.

Cleaning your inhaler
To stop your inhaler blocking, it is important to clean it at least once a week.
To clean your inhaler:

- Remove the mouthpiece cover.
 - Do not remove the metal canister from the plastic casing at any time.
 - Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.
 - Replace the mouthpiece cover. It will ‘click’ into place when fitted correctly. If it does not ‘click’ into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.
- Do not put the metal container in water.

If you use more Seretide than you should
It is important to use the inhaler as instructed. If you accidentally take a larger dose than recommended, talk to your doctor or pharmacist. You may notice your heart beating faster than usual and that you feel shaky. You may also have a headache, muscle weakness and aching joints.

If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of Seretide may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Seretide
If you forget to use your inhaler, take your next dose when it is due. Do not take a double dose to replace the one you forgot.

If you stop using Seretide
It is very important that you take your Seretide every day as directed. Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Seretide. This could make your breathing problem worse and very rarely side effects could occur.

- These include:
- Stomach pain
 - Tiredness and loss of appetite
 - Sickness and diarrhoea
 - Weight loss
 - Headache or drowsiness
 - Low levels of potassium in your blood
 - Low blood pressure and seizures

Very rarely, if you get an infection or at times of extreme stress (such as after a serious accident or if you have surgery), you may get similar side effects. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids (like prednisolone).

If you have any further questions on using the inhaler, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Seretide can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of Seretide to control your asthma.

Allergic reactions: you may notice your breathing suddenly gets worse after using Seretide. You may be very wheezy and cough. You may also notice itching and swelling (usually of the face, lips, tongue, or throat). **If you get these effects or if they happen suddenly after using Seretide, tell your doctor straight away.** Allergic reactions to Seretide are uncommon (they affect less than 1 person in 100).

Other side effects are listed below:
Very Common (affects more than 1 person in 10)

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

Common (affects less than 1 person in 10)

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue and hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately after taking each puff may help. Your doctor may prescribe an anti fungal medication to treat the thrush.
- Aching, swollen joints and muscle pain.
- Muscle cramps

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):

- Pneumonia and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum colour, fever, chills, increased cough, increased breathing problems
- Bruising and fractures
- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache)
- A reduction in the amount of potassium in the blood (you may get an uneven heart beat, muscle weakness, cramp).

Uncommon (affects less than 1 person in 100)

- Increases in the amount of sugar (glucose) in your blood (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- Cloudy lens in the eye
- Very fast heart beat (tachycardia).
- Feeling shaky and fast or uneven heart beat (palpitations) - these are usually harmless and get less as treatment continues.
- Chest pain.

- Feeling worried (this effect mainly occurs in children).
 - Disturbed sleep
 - Rash
- Rare (affects less than 1 person in 1000)**
- **Breathing difficulties or wheezing that get worse straight after taking Seretide.** If this happens **stop using your Seretide inhaler.** Use your fast-acting ‘reliever’ inhaler to help your breathing and **tell your doctor straight away.**
 - Seretide may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects include:
 - Slowing of growth in children and adolescents
 - Thinning of the bones
 - Glaucoma
 - Weight gain
 - Rounded (moon shaped) face (Cushing’s Syndrome).Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of Seretide to control your asthma.
 - Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
 - Uneven heartbeat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Seretide unless they tell you to stop.

Frequency not known, but may also occur:

- Depression or aggression. These effects are more likely to occur in children.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SERETIDE

- **Keep out of the reach and sight of children.**
 - Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.
 - Do not store above 25°C.
 - Do not store Seretide Evohaler in a cold place, as your medicine may not work as well.
 - Do not use Seretide after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
 - The metal can contains a pressurised liquid. Do not puncture, break or burn it even if you think it is empty.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Seretide contains

- The active substance(s) are 25 micrograms salmeterol (as salmeterol xinafoate) and 250 micrograms fluticasone propionate.
- The other ingredient is norflurane (HFA 134a).

What Seretide looks like and contents of the pack

- Seretide Evohaler is supplied to you in a metered dose inhaler which delivers your medicine in a pressurised suspension for you to inhale.
- The pressurised can contains a white to off white suspension for inhalation.
- The devices are packed in cartons of 1 Evohaler, containing 120 metered doses.

Procured from within the EU by the Parallel Product Authorisation Holder: Clear Pharmacy 157-173 Roden Road, Belfast, BT12 5QA, United Kingdom.

Manufacturers

- Glaxo Wellcome Production, Zone Industrielle, No.2, 23 Rue Lavoisier, la Madeleine, 27000 Evreux, France.
- Glaxo Wellcome S.A., Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain.
- GlaxoWellcome GmbH and Co KG, Industriestrasse 32-36 D-23843, Bad Oldesloe, Germany.

Repackager

- Pharmaram Limited, Unit F4 Tom Bill Way, Ashby de la Zouch, Leicestershire. LE65 2UY, UK.

This medicine is authorised in Italy as Seretide.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Seretide Dosieraerosol	Ireland	Seretide Evohaler
Belgium	Seretide	Italy	Seretide
Denmark	Seretide	Luxembourg	Seretide
Finland	Seretide Evohaler	The Netherlands	Seretide
France	Seretide	Portugal	Seretaide Inalador
Germany	atmadisc	Spain	Seretide
Greece	Seretide Inhaler	Sweden	Seretide Evohaler
Iceland	Seretide	United Kingdom	Seretide Evohaler

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Detailed information on this medicine is available on the web site of the Irish Medicines Board.

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