

PACKAGE LEAFLET: INFORMATION FOR THE USER

Seretide 25 micrograms/50 micrograms/dose - pressurized inhalation, suspension.
Seretide 25 micrograms/125 micrograms/dose - pressurized inhalation, suspension.
Seretide 25 micrograms/250 micrograms/dose - pressurized inhalation, suspension.

Salmeterol / Fluticasone propionate

Read the entire package leaflet carefully before you start using this medicine.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. 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.

This package leaflet contains:

1. What is Seretide and what is it used for?
2. What do you need to know before you use Seretide?
3. How to use Seretide?
4. What are the possible side effects?
5. How to store Seretide?
6. Further information

1. WHAT IS SERETIDE AND WHAT IS IT USED FOR?

Seretide contains 2 medicines, salmeterol and fluticasone propionate.

Salmeterol is a long-acting bronchodilator. Bronchodilators help to open the airways in the lungs, making it easier to breathe in and out. The effect of Salmeterol lasts for at least 12 hours.

Fluticasone propionate is a corticosteroid that reduces edema and pulmonary irritation.

The doctor has prescribed this medication to prevent breathing problems such as asthma.

Seretide must be used daily as directed by the doctor to ensure asthma is well controlled.

Seretide prevents the development of episodes of shortness of breath and wheezing. It is not effective if the symptoms of breathlessness or wheezing are already present. In these cases, a 'rescue medication' with rapid onset of action must be used, such as Salbutamol.

2. WHAT SHOULD YOU CONSIDER BEFORE USING SERETIDE?

SERETIDE must not be used,

If you are hypersensitive (allergic) to Salmeterol, Fluticasone propionate, or any other ingredient of the medication, Norflurane (HFA134a).

Special caution is required when using SERETIDE,

Your doctor will monitor your treatment more closely if you suffer from any of the following conditions:

- Heart disease including irregular or too fast heartbeat,
- Hyperthyroidism
- Arterial hypertension,
- Diabetes (Seretide can increase your blood sugar levels),
- Low potassium levels in the blood,
- Current or past tuberculosis (TB).

Inform your doctor if you have already suffered from these conditions before using Seretide.

Using Seretide with other medications

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used other medications, even if they are for asthma or over-the-counter medications. It is possible that using Seretide with other medications is not suitable.

Inform your doctor if you are using/taking any of the following medicines before starting to use Seretide:

- Beta-blockers (for example Atenolol, Propranolol, Sotalol). Beta-blockers are mainly used to treat high blood pressure and other heart diseases.
- Medicines against viruses or fungi (such as Ritonavir, Ketoconazole, and Itraconazole). Some of these medicines can increase the amount of Fluticasone propionate or Salmeterol in your body. This can increase the risk of side effects from Seretide such as irregular heartbeat, or the side effects may worsen.
- Corticosteroids (for oral use or as an injection). If you have recently been given these medicines, the risk of adrenal impairment from this medicine may be increased.

Pregnancy and breastfeeding

Consult your doctor if you are pregnant, planning to become pregnant, or breastfeeding before using Seretide. Your doctor will assess whether you can use Seretide during this period.

Driving and using machines

It is unlikely that Seretide will affect your ability to drive or use machines.

3. HOW TO USE SERETIDE?

Use Seretide daily unless your doctor advises you to stop.

Always use Seretide exactly as your doctor has instructed. Do not use more than the recommended dose. Ask your doctor or pharmacist if you are not sure.

Adults and adolescents aged 12 years and over

- Seretide 25/50, suspension – Two inhalations twice daily
- Seretide 25/125, suspension – Two inhalations twice daily
- Seretide 25/250, suspension – Two inhalations twice daily

Children between 4 and 12 years

Seretide 25/50, suspension – Two inhalations twice daily

The use of this medicine is not recommended for children under 4 years.

It is possible that your asthma symptoms can be well controlled if you use Seretide twice daily. If this is the case, your doctor may decide to reduce the dose to once daily. The application can be changed as follows:

once in the evening if you have symptoms at night.

once in the morning if you have symptoms during the day.

It is very important that you follow your doctor's instructions regarding the number of inhalations and frequency of use of your medication.

If you are using Seretide for asthma, your doctor will want to regularly check your symptoms. If the asthma worsens or you experience more severe breathing problems, inform your doctor immediately. You may experience wheezing more frequently, feel chest tightness more often, or need to use your fast-acting rescue medication more frequently. If this is the case, you must continue to use Seretide, but you must not change the number of inhalations. It is possible that your respiratory condition is worsening and you may become seriously ill. Contact your doctor as you may need additional treatment.

Method of application:

Your doctor, nurse, or pharmacist will show you how to use your inhaler correctly. They will check from time to time how you are using it. If you do not use Seretide Diskus correctly or do not follow the instructions for use, asthma or COPD will not be treated as required.

The medication is contained in a pressurized canister located in a plastic mouthpiece. The canister is equipped with a counter that shows the number of remaining puffs. Each time the canister is pressed, a puff of medication is released and the number on the counter decreases by one.

Please be careful not to drop the metered-dose inhaler, as this could trigger the counter to count down.

Testing your metered-dose inhaler:

1. When using the device for the first time, check its correct function. Remove the cap from the mouthpiece by holding the device between your thumb and forefinger at the sides. Gently press against the sides of the cap and pull it off.
2. To ensure the metered-dose inhaler is working, shake it vigorously. Point the mouthpiece away from you, press the canister, and release puffs into the air. Repeat these steps, shaking the device before each puff, until the counter reads 120. If the metered-dose inhaler has not been used for a week or longer, release two puffs into the air.

Using your metered-dose inhaler:

It is important to inhale as slowly as possible before using your metered-dose inhaler.

1. During inhalation, you should stand or sit.

2. Remove the protective cap from the mouthpiece (as shown in the first image). Ensure that the mouthpiece is clean inside and out and free of particles.
3. Shake the device four to five times to ensure that loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the metered-dose inhaler upright between fingers and thumb, with the thumb under the mouthpiece. Breathe out as deeply as possible.
5. Place the mouthpiece in your mouth and close your lips firmly around it, but do not bite down.
6. Inhale through your mouth. Press firmly on the top of the container immediately after you start inhaling to release a spray. Continue to inhale evenly and deeply.
7. While holding your breath, remove the mouthpiece and take your finger off the top of the medication container. Continue to hold your breath for a few seconds or as long as possible.
8. Wait about half a minute between inhalations of each spray, repeat steps 3 to 7.
9. Rinse your mouth with water and spit it out, as this helps prevent thrush and hoarseness.
10. Always replace the cap immediately after use to protect the mouthpiece from dust. Press the cap firmly until you hear a click, then the cap is properly seated. If you do not hear a click, turn the mouthpiece cap over and try again. Do not use force.

If you or your child find it difficult to use the aerosol, an inhalation device such as Volumatic or Aerochamber Plus can be used. Consult your doctor, healthcare provider, or pharmacist before using the inhalation device for the first time or if you are using a different inhalation device.

You should get another metered-dose inhaler when the counter shows "020". Do not use the device any longer when the counter shows 000, as any remaining spray in the device may not be sufficient to release a full dose. You should neither attempt to change the number on the counter nor separate the counter from the medication container.

Cleaning your metered-dose inhaler:

To avoid clogging, it is important to clean the metered-dose inhaler at least once a week.

Please note the following:

Remove the protective cap.

Do not separate the medication container from the plastic applicator during cleaning or at any other time.

Wipe the mouthpiece and the plastic applicator inside and outside with a dry and clean cloth or tissue.

Replace the cap on the mouthpiece until you hear a click, then the cap is properly seated. If you do not hear a click, turn the mouthpiece cap over and try again. Do not use force.

The medication container must not be immersed in water.

If you have used more SERETIDE than you should If you have used or taken too much Seretide, contact your doctor, pharmacist, or the poison control center (070/245.245) immediately.

It is very important that you use Seretide according to your doctor's instructions. If you accidentally used a higher dose than recommended, inform your doctor or pharmacist. You may notice that your heart beats faster than usual and that you tremble. You may also experience headaches, muscle weakness, and joint pain.

If you have used high doses over a long period, ask your doctor or pharmacist for advice, as high doses of Seretide could reduce the production of steroid hormones by the adrenal glands.

If you forget to use SERETIDE

Apply the next dose at the usual time if you have forgotten to use your medication. Do not apply a double dose if you have forgotten the previous application.

If you stop using SERETIDE

It is very important that you use Seretide daily as instructed by your doctor. Use it as long as your doctor advises you to. Do not suddenly stop using Seretide or suddenly reduce the dose. This could lead to a worsening of your breathing problems and, in rare cases, side effects such as:

- Abdominal pain
- Fatigue and loss of appetite
- Nausea and diarrhea
- Weight loss
- Headache or drowsiness
- Reduction of potassium levels in the blood
- Hypotension and seizures

In very rare cases, you may experience such side effects if you get an infection or are under stress (for example, after a serious accident or surgery).

To prevent such symptoms from occurring, your doctor may prescribe additional corticosteroids (such as prednisolone).

If you have further questions about the use of the medication, ask your doctor or pharmacist.

4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, Seretide can have side effects, but they do not occur in everyone. To reduce the risk of side effects, your doctor will prescribe the lowest possible dose that can control your asthma.

Allergic reactions: You may notice that your breathing suddenly worsens after using Seretide. You may have a severely wheezing breath and cough a lot. It is also possible that you experience itching (pruritus) and notice swelling (usually in the face, lips, tongue, or throat). Inform your doctor immediately if you notice such symptoms or if they occur suddenly after using Seretide. Allergic reactions to Seretide occur occasionally (affecting less than one person in 100).

The following other side effects may occur:

Very common (affect more than one person in 10)

Headaches: They usually improve with continued treatment.

In patients with COPD, a more frequent occurrence of rhinitis has been reported.

Common (affecting less than one person in 10)

Candidiasis in the mouth and throat (pain, white-yellowish raised patches) also pain on the tongue and hoarseness. It may be useful to rinse your mouth with water after each inhalation and spit it out immediately. Your doctor will prescribe an antifungal medication to treat oral candidiasis (thrush).

Joint pain, joint swelling, and muscle pain.

The following side effects have also been observed in patients with chronic obstructive pulmonary disease (COPD):

Pneumonia and bronchitis (lung infection). Inform your doctor if you notice any of the following symptoms: increased sputum, change in sputum color, fever, chills, increased coughing, increased breathing problems

Bruising and bone fractures

Sinusitis (feeling of tension or congestion in the nose, cheeks, and behind the eyes, sometimes associated with a throbbing pain).

Reduction of potassium levels in the blood (which can lead to irregular pulse, muscle weakness, and cramps).

Occasionally (affecting less than one person in 100)

Very rapid pulse (tachycardia)

Tremors and rapid or irregular pulse (palpitations). These effects are also harmless and decrease with continued treatment.

Muscle cramps

Anxiety (this effect mainly occurs in children).

Sore throat. It may be useful to rinse your mouth with water after each inhalation and spit it out immediately.

Rare (affecting less than one person in 1000)

Breathing problems or wheezing with worsening immediately after using Seretide. If this occurs, stop using your Seretide inhaler. Use your 'rescue inhaler' with rapid onset of action to help you breathe and contact your doctor immediately.

Seretide can affect the normal production of steroid hormones in the body, especially if you have used higher doses for a long period.

This can manifest as follows:

- Growth retardation in children and adolescents,
- Bone loss
- Cataract and glaucoma
- Weight gain

- Round face (moon face) (Cushing's syndrome)

Your doctor will regularly check you for these side effects and ensure that you use the lowest possible dose of Seretide to control your asthma.

Increase in blood sugar levels (glucose levels) in your blood (hyperglycemia)

If you are diabetic, more frequent monitoring of blood sugar levels and possibly an adjustment of your usual antidiabetic treatment may be necessary.

Sleep disturbances and behavioral changes with unusual hyperactivity or irritability (these effects mainly occur in children).

Irregular pulse or extra heartbeats (arrhythmia). Inform your doctor, but do not stop using Seretide unless your doctor advises you to.

Rash

Frequency not known, but possible occurrence:

Depression or aggression. These side effects are more common in children.

Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects not listed in this leaflet.

5. HOW TO STORE SERETIDE?

Keep medicines out of the reach of children.

Immediately after use, always replace the cap after use. Press the cap firmly until you hear a click. Do not use force.

Do not store above 25°C.

Do not store Seretide in a cold environment, as the therapeutic effect of this medicine may then decrease.

Do not use the medicine after the expiry date stated on the label and carton after EXP. The expiry date refers to the last day of the month.

The active substance container contains a pressurized inhalation. It should not be pierced, forcibly opened, or burned, even if it appears to be empty.

The medicine must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of the medicine when you no longer need it. This measure helps protect the environment.

6. FURTHER INFORMATION

What SERETIDE contains

The active substances are Salmeterol (as salmeterol xinafoate) (25 micrograms) and Fluticasone propionate (50, 125, or 250 micrograms).

The other ingredient is Norflurane (134a).

What SERETIDE looks like and contents of the pack

Seretide is available in a metered-dose inhaler that releases your medicine in the form of a suspension for pressurized inhalation.

The pressurized container contains a white to nearly white suspension for inhalation.

The metered-dose inhalers are available in packs of 1, 3, or 10 units.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturers

Marketing authorization holder

GlaxoSmithKline Pharmaceuticals s.a./n.v.

Site Apollo

Avenue Pascal, 2-4-6

B-1300 Wavre

Manufacturers

Glaxo Wellcome Production

Zone Industrielle 2

23 rue Lavoisier

F-27000 Evreux

France

Glaxo Wellcome S.A.

Avenida de Extremadura, 3

E - 09400, Aranda de Duero, Burgos, Spain

Tel: +34 947 529 700; Fax: +34 947 529 800

GlaxoWellcome GmbH and Co KG

Industriestrasse 32-36

D-23843, Bad Oldesloe, Germany

This medicinal product is authorized in the Member States of the European Economic Area (EEA) under the following names:

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

Type of supply

Prescription only.

Marketing authorization numbers

Seretide 25 micrograms/50 micrograms/dose

BE220683

Seretide 25 micrograms/125 micrograms/dose BE220692
Seretide 25 micrograms/250 micrograms/dose BE220701

This leaflet was last approved in

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