

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Seretide Diskus 50 micrograms/100 micrograms/dose, pre-dispensed powder for inhalation  
Seretide Diskus 50 micrograms/250 micrograms/dose, pre-dispensed powder for inhalation  
Seretide Diskus 50 micrograms/500 micrograms/dose, pre-dispensed powder for inhalation

Salmeterol / Fluticasone propionate

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

- Keep the package leaflet. You may want to read it again later.
- If you have further questions, please 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This package leaflet includes:

1. What is Seretide and what is it used for?
2. What do you need to know before using 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 widen the bronchi 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.

Your doctor has prescribed this medication to prevent breathing problems such as:

Asthma

Chronic obstructive pulmonary disease (COPD). At a dose of 50/500 micrograms, Seretide Diskus reduces the number of COPD exacerbations.

Seretide must be used daily as directed by your doctor to effectively control asthma and COPD symptoms.

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

### 2. WHAT SHOULD YOU CONSIDER BEFORE USING SERETIDE?

SERETIDE must not be used if

You are hypersensitive (allergic) to salmeterol xinafoate, fluticasone propionate, or any other ingredient of the medication, lactose monohydrate.

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 if you are taking/using other medicines or have recently taken/used them, even if they are medicines for asthma or non-prescription medicines. It is possible that the use of Seretide with other medicines is not suitable.

Inform your doctor if you are using/taking any of the following medicines before you start using 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 the 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.

Important information about some of the other ingredients of Seretide

Each dose of Seretide Diskus contains up to 12.5 milligrams of lactose. The amount of lactose present in this medicine usually does not cause problems for people with lactose intolerance.

### 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.

## For asthma

### Adults and adolescents aged 12 years and over

Seretide 50/100 Diskus – one inhalation twice daily

Seretide 50/250 Diskus – one inhalation twice daily

Seretide 50/500 Diskus – one inhalation twice daily

### Children between 4 and 12 years

Seretide 50/100 Diskus – one inhalation twice daily

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

### In adults suffering from chronic obstructive pulmonary disease (COPD)

Seretide 50/500 Diskus – one inhalation twice daily

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 on 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 more frequent wheezing, 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, however, you must not change the number of inhalations. It is possible that your respiratory disease is worsening and you become seriously ill. Contact your doctor as you may need additional treatment.

### Method of administration:

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

The Diskus contains blister packs with Seretide in powder form

A counter on the Diskus shows the number of doses remaining. It counts down to 0, with the numbers 5 to 0 appearing in red to alert you that only a few doses are left.

When the counter shows 0, your inhalation device is empty.

### Instructions for use of your inhaler

1. To open the Diskus, hold the outer casing with one hand and press lightly on the designated part with the thumb of the other hand. Press the thumb as far as possible. When a click is heard, a small gap opens in the mouthpiece.

2. Hold the Diskus so that the mouthpiece is facing you. You can hold it in either the right or left hand. Push the lever as far out as possible. When a click is heard, a dose of the medication is released into the mouthpiece.

Each time you push the lever back, a blister pack inside is opened and the powder is ready for inhalation. Do not operate the lever unnecessarily, as the doses released in this way will be lost.

3. Hold the Diskus away from your mouth. Breathe out as deeply as possible. Do not blow into the Diskus.
4. Place the mouthpiece to your lips and close your lips around it. Inhale quickly and as deeply as possible through your mouth through the Diskus, not through your nose. Remove the Diskus from your mouth. Hold your breath for about 10 seconds or as long as possible. Breathe out slowly.
5. Rinse your mouth with water and spit it out. This will prevent the occurrence of candidiasis and hoarseness.
6. Close the Diskus by placing your thumb on the designated spot and moving the movable part of the inhaler as far towards you as possible. A click will be heard. The lever returns to its original position and is moved back to the starting position.

Your Diskus is ready for use again.

#### Cleaning the Diskus

Wipe the mouthpiece of the Diskus with a dry cloth to clean it.

If you have used more SERETIDE than you should

If you have used or taken too much Seretide, contact your doctor, pharmacist, or 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 suffer from headaches, muscle weakness, and joint pain.

If you have used high doses for 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 according to your doctor's instructions. Use it until your doctor advises you to stop. 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 could occur such as:

- Abdominal pain
- Fatigue and loss of appetite
- Nausea and diarrhea
- Weight loss
- Headaches 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 medicine, ask your doctor or pharmacist.

#### 4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, Seretide can have side effects, but not everyone will experience them. To reduce the risk of side effects, your doctor will prescribe the lowest possible dose that can control your asthma or COPD.

**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 on 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 (they affect 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 (affect 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 helpful 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

Bruises and bone fractures

Inflammation of the sinuses (feeling of pressure 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 helpful 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 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 do so.

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.

Do not store above 30°C.

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

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer need. This measure helps protect the environment.

## 6. FURTHER INFORMATION

### What SERETIDE contains

The active substances are salmeterol (as salmeterol xinafoate) (50 micrograms) and fluticasone propionate (100, 250, or 500 micrograms).

The other ingredient is lactose monohydrate (contains milk protein).

### What SERETIDE looks like and contents of the pack

Seretide Diskus contains an aluminum foil strip. The aluminum protects the inhalation powder from atmospheric effects.

Each dose is packed in a single-dose container.

The dosing chambers are packed in cartons with the following contents:

1 x Diskus 28 inhalations

or 1, 2, 3 or 10 x Diskus each with 60 inhalations

Not all pack sizes may be marketed.

### Pharmaceutical company and manufacturer

#### Pharmaceutical company

GlaxoSmithKline Pharmaceuticals s.a./n.v.

Site Apollo

Avenue Pascal, 2-4-6

B-1300 Wavre

#### Manufacturer

Glaxo Wellcome Production  
Zone Industrielle 2  
23 rue Lavoisier  
F-27000 Evreux  
France

Glaxo Wellcome GmbH & Co  
Industriestrasse 32-36  
D-23843 Bad Oldesloe  
Germany

Glaxo Operations UK  
Limited (trading as Glaxo  
Wellcome Operations)  
Priory Street  
Ware, Hertfordshire  
SG12 0DJ  
United Kingdom

This medicine is authorized in the member states of the European Economic Area (EEA) under the following names:

Austria	Seretide Diskus
Belgium	Seretide Diskus
Denmark	Seretide
Finland	Seretide Diskus
France	Seretide Diskus
Germany	atmadisc Diskus
Greece	Seretide Diskus
Ireland	Seretide Diskus
Italy	Seretide Diskus
Luxembourg	Seretide Diskus
Netherlands	Seretide Diskus

Portugal	Seretide Diskus
Spain	Seretide Accuhaler
Sweden	Seretide Diskus
United Kingdom	Seretide Accuhaler

Prescription type  
Prescription only.

Marketing authorization numbers

SERETIDE DISKUS 50 micrograms/100 micrograms/dose	BE200855
SERETIDE DISKUS 50 micrograms/250 micrograms/dose	BE200873
SERETIDE DISKUS 50 micrograms/500 micrograms/dose	BE200882

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