

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a physician's prescription only

Seretide Diskus 50/100 mcg, Powder for Inhalation

Each dose contains 50 micrograms salmeterol (as Xinafoate)/
100 micrograms fluticasone propionate inhalation powder.

Seretide Diskus 50/250 mcg, Powder for Inhalation

Each dose contains 50 micrograms salmeterol (as Xinafoate)/
250 micrograms fluticasone propionate inhalation powder.

Seretide Diskus 50/500 mcg, Powder for Inhalation

Each dose contains 50 micrograms salmeterol (as Xinafoate)/
500 micrograms fluticasone propionate inhalation powder.

For the list of the inactive and allergenic ingredients see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Additional information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Seretide Diskus contains two active ingredients: 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 effect last for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

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

- Asthma
- COPD – Seretide Diskus, at a dose of 50/250 and 50/500 micrograms, is also indicated to treat chronic obstructive pulmonary disease (COPD). The medicine reduces the number of flare-ups of COPD symptoms.

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

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

Therapeutic group

Salmeterol is a β-2 receptor agonist.

Fluticasone propionate is a corticosteroid.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

If you are sensitive (allergic) to salmeterol, fluticasone propionate or to the inactive ingredient lactose monohydrate contained in the medicine as listed in section 6.

Special warnings regarding the use of the medicine

Before treatment with Seretide Diskus, tell your physician if you have:

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

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

Children and adolescents

- Seretide Diskus is not recommended for use in children below 4 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including medicines for asthma, non-prescription medicines or nutritional supplements, tell the physician or the pharmacist. This is because Seretide Diskus may not be suitable to be taken with some other medicines. Inform the physician or the pharmacist if you are taking the following medicines, before starting to use Seretide Diskus:

- β-blockers (such as: atenolol, propranolol, sotalol). β-blockers are mostly used to treat high blood pressure or other heart conditions.
- Medicines to treat infections (such as: ketoconazole, itraconazole and erythromycin), including certain medicines to treat HIV infection (such as: ritonavir and cobicistat-containing medicines). 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 Diskus, including irregular heart beats, or may make side effects worse. If you take these medicines, your physician may want to closely monitor your condition.
- Corticosteroids (by mouth or by injection). If you recently took these medicines, it might increase the risk of this medicine affecting your adrenal gland.
- Diuretics, used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).

- Xanthine medicines, these medicines are often used to treat asthma.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before using the medicine.

Driving and using machines

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

Important information about some of the ingredients of the medicine

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. Use your Seretide Diskus every day until your physician advises you to stop.

Do not take more than the recommended dosage.

Do not stop taking Seretide Diskus or reduce the dosage without first talking to your physician.

Seretide Diskus should be inhaled through the mouth into the lungs.

You may not be able to feel the texture or taste of the powder on your tongue, even if you used the Diskus inhaler correctly.

The dosage and treatment regimen will be determined by the physician only.
The usual dosage is generally:

For asthma

Adults and adolescents aged 12 years and over

- Seretide Diskus 50/100 mcg – One inhalation twice a day.
- Seretide Diskus 50/250 mcg – One inhalation twice a day.
- Seretide Diskus 50/500 mcg – One inhalation twice a day.

Children 4 to 12 years of age

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

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- Seretide Diskus 50/250 mcg – One inhalation twice a day.
- Seretide Diskus 50/500 mcg – One inhalation twice a day.

Your symptoms may become well controlled using Seretide Diskus twice a day. If so, your physician may decide to reduce your dosage to once a day.

The dosage 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 physician's instructions on how many inhalations to take and how often to take your medicine.

Do not exceed the recommended dose.

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

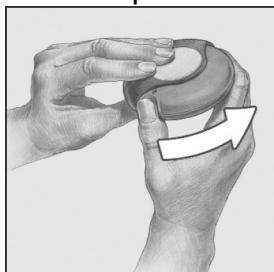
If your asthma or breathing gets worse, tell your physician straight away. You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast acting 'reliever' medicine. If any of these happen, continue to take Seretide Diskus but do not increase the number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

Instructions for use

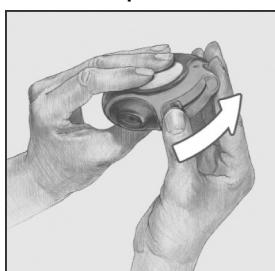
- Your physician, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using Seretide Diskus properly or as prescribed may mean that it will not help your asthma or COPD as it should.
- The Diskus inhaler holds blisters containing the medicine Seretide Diskus as a powder.
- There is a counter on top of the Diskus 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 Diskus, 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.

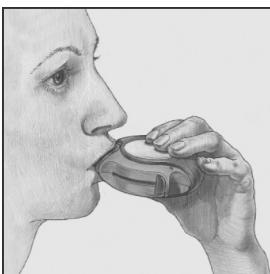


2. Hold your Diskus with the mouthpiece facing towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece.



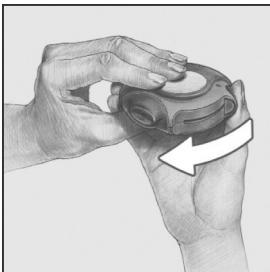
Every time the lever is pulled back, a blister is opened inside the inhaler and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.

3. Hold the Diskus away from your mouth, breathe out as far as is comfortable. Do not breathe into your Diskus.
4. Put the mouthpiece to your lips; breathe in steadily and deeply through the Diskus, not through your nose.
Remove the Diskus 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 prevent you from getting thrush and becoming hoarse.
6. To close the Diskus, 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 will reset.



Your Diskus is now ready for you to use again.

As with other inhalers, caregivers should ensure that children prescribed Seretide Diskus use correct inhalation technique, as described above.

Cleaning your inhaler

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

If you accidentally inhaled a higher dosage

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

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

If you inhaled an overdose or if a child has accidentally inhaled the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to use Seretide Diskus

If you forgot to inhale this medicine at the designated time, do not inhale a double dose to compensate for the forgotten dose. Inhale the next dose at the usual time and consult the physician.

Adhere to the treatment regimen recommended by the doctor.

If you stop using Seretide Diskus

It is very important that you take your Seretide Diskus every day as directed.

Keep taking it until your physician tells you to stop. Do not stop or suddenly reduce your dose of Seretide Diskus. This could make your breathing worse.

In addition, if you suddenly stop taking Seretide Diskus or reduce your dose of Seretide Diskus, this may (very rarely) cause you to have problems with your adrenal gland (adrenal insufficiency) which sometimes causes side effects.

These side effects may include any of the following:

- Stomach pain
- Tiredness and loss of appetite, feeling sick
- Sickness and diarrhea
- Weight loss
- Headache or drowsiness
- Low levels of sugar in your blood
- Low blood pressure and seizures (fits)

When your body is under stress such as fever, trauma (such as a car accident), infection or surgery, adrenal insufficiency can get worse and you may have any of the side effects listed above.

If you get any side effects, talk to your physician or pharmacist. To prevent these symptoms from occurring, your physician may prescribe extra corticosteroids in tablet form (such as prednisolone).

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Seretide Diskus may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

To reduce the chance of side effects, your physician will prescribe the lowest dose of Seretide Diskus to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Seretide Diskus. You may be very wheezy and

cough or be short of breath. You may also notice itching, a rash (itchy lumps [hives]) and swelling (usually of the face, lips, tongue or throat), or you may suddenly feel that your heart is beating very fast or you feel faint or light headed (which may lead to collapse or loss of consciousness). **If you get any of these effects or if they happen suddenly after using Seretide Diskus, stop using Seretide Diskus and refer immediately to the physician.** Allergic reactions to Seretide Diskus are uncommon (they affect less than 1 person in 100).

Pneumonia (infection of the lung) in COPD patients (common side effect)

Tell your physician if you have any of the following effects while using Seretide Diskus. They could be symptoms of a lung infection:

- fever or chills
- increased mucus production, change in mucus color
- increased cough or increased breathing difficulties

Other side effects are listed below:

Very common side effects (affect 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 side effects (affect less than 1 person in 10)

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue, hoarse voice and throat irritation. Rinsing your mouth with water and spitting it out immediately and/or brushing your teeth after taking each dose of your medicine may help. Your physician 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):

- Bruising and fractures.
- Inflammation of the 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, cramps).

Uncommon side effects (affect less than 1 person in 100)

- Increase in the amount of sugar (glucose) in your blood (hyperglycemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- Cataract (cloudy lenses in the eye).
- Very fast heart beat (tachycardia).
- Feeling shaky (tremor) 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.
- Allergic skin rash.

Rare side effects (affect less than 1 person in 1,000)

- **Breathing difficulties or wheezing that get worse straight after taking Seretide Diskus.** If this happens, **stop using your Seretide Diskus.** Use your fast acting ‘reliever’ inhaler to help your breathing and **tell your physician straight away.**
- Seretide Diskus 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 physician will check you regularly for any of these side effects and make sure you are taking the lowest dose of Seretide Diskus to control your asthma.
- Behavioral changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heart beat or heart gives an extra beat (arrhythmias). Tell your physician, but do not stop taking Seretide Diskus unless the physician tells you to stop.
- A fungal infection in the esophagus, which might cause difficulties in swallowing.

Side effects of unknown frequency, but which may also occur:

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

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the physician.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.

6. ADDITIONAL INFORMATION

- **In addition to the active ingredients, the medicine also contains –**
lactose monohydrate (which contains milk proteins).
- **What the medicine looks like and the content of the package –**
The Diskus inhaler contains a foil strip that divides the powder for inhalation into measured doses and protects it from contact with air.
The device is packed in a box which holds 1 Diskus containing 60 doses for inhalation.
- **License Holder:** GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- **Manufacturer:** Glaxo Wellcome Production, Evreux, France.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Seretide Diskus 50/100 mcg: 114-13-29551
Seretide Diskus 50/250 mcg: 114-15-29553
Seretide Diskus 50/500 mcg: 114-14-29552

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