

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed according to a physician's prescription only

Serevent Inhaler CFC Free, Suspension for Inhalation

Each actuation (puff) releases a metered dose of 25 micrograms of salmeterol (as xinafoate)

Salmeterol (as xinafoate) 25 mcg/actuation

For the list of the inactive ingredients in the medicine, see 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 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?

This medicine is intended for:

- patients with asthma (including nocturnal asthma) who are inadequately controlled on inhaled corticosteroids.
- treatment of Chronic Obstructive Pulmonary Disease (COPD).
- prevention of exercise-induced asthma.

Therapeutic group:

Selective beta-2-adrenoreceptor agonists.

Serevent Inhaler contains the medicine salmeterol. This medicine is a 'long-acting bronchodilator'. It helps the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects are usually felt within 10 to 20 minutes and last for 12 hours or more.

Serevent Inhaler helps to stop breathlessness and wheezing coming on. It

does not work once you are breathless or wheezy. If that happens, you need to use a fast-acting 'reliever' medicine, such as salbutamol.

The medicine is supplied to you in an inhaler. You breathe the medicine directly into your lungs.

Serevent Inhaler contains norflurane. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Serevent Inhaler.

This will make no difference to how your medicine works.

If you are being treated for asthma, you should always be given both a Serevent Inhaler and a steroid inhaler to use together.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

you are sensitive (allergic) to the active ingredient {salmeterol (as xinafoate)} or to the additional ingredient {norflurane (HFA 134a)}.

Special warnings regarding use of the medicine

- **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, do not increase your number of puffs of Serevent Inhaler. Your chest condition may be getting worse and you could become seriously ill. See your physician as you may need a change in asthma treatment.
- Once your asthma is well controlled your physician may consider it appropriate to gradually reduce the dosage of Serevent Inhaler.
- If you have been prescribed Serevent Inhaler for your asthma, continue to use any other asthma medication you are already taking. These could include a steroid inhaler or steroid tablets. Continue taking the same doses as before, unless your physician tells you otherwise. Do this even if you feel much better. **Do not stop taking your steroid inhaler (or any steroid tablets) when you start using Serevent Inhaler.**
- Your physician may want to check your health regularly if you have an overactive thyroid gland, diabetes mellitus (Serevent Inhaler may increase

your blood sugar) or heart disease, including an irregular or fast heartbeat.

Children and adolescents

The medicine is not intended for children under the age of 4.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

- This includes medicines for asthma or any other medicines obtained without a prescription. This is because Serevent Inhaler may not be suitable to be taken with other medicines.
- Please inform your physician before using Serevent Inhaler if you are currently being treated for any fungal infections with medicines containing ketoconazole or itraconazole, or if you are being treated for HIV with ritonavir. These medicines may increase the risk of you experiencing side effects with Serevent Inhaler, including irregular heartbeats, or may make side-effects worse.
- Beta-blockers should be avoided when taking Serevent Inhaler, unless your physician tells you to take them. Beta-blockers, including atenolol, propranolol and sotalol, are mostly used for high blood pressure or other heart conditions. Please tell your physician if you are taking beta-blockers or have recently been prescribed beta-blockers as they may reduce or abolish the effects of salmeterol.
- Serevent Inhaler can reduce the amount of potassium in your blood. If this happens, you may notice an uneven heartbeat, muscle weakness or cramp. This is more likely to happen if you take Serevent Inhaler with some medicines used to treat high blood pressure (diuretics) and other medicines used to treat breathing problems such as theophylline or steroids. Your physician may ask for you to have blood tests to check the amount of potassium in your blood. If you have any concerns, consult your physician.

Pregnancy and breast-feeding

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

Driving and using machines

The possible side effects associated with Serevent Inhaler are unlikely to affect your ability to drive or use machines.

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 preparation dosage and treatment regimen.

- **If you are being treated for asthma, you should always be given both a Serevent Inhaler and a steroid inhaler to use together.**
- Use Serevent Inhaler every day, until your physician advises you to stop.
- You will start to feel your medicine working within the first day of use.

Serevent Inhaler is intended for inhalation by mouth only.

The dosage and treatment regimen will be determined by the physician only. The recommended dosage is usually:

Adults with Asthma

- The usual starting dose is 2 puffs twice a day.
- For people with more severe asthma, the physician may increase the dose to 4 puffs twice a day.

Children with Asthma

- In children over the age of 4 the usual dose is 2 puffs twice a day.
- Serevent Inhaler is not intended for use in children below 4 years of age.

Adults with Chronic Obstructive Pulmonary Disease (COPD) including bronchitis and emphysema

- The usual starting dose is 2 puffs twice a day.
- Not intended for children and adolescents.

Do not exceed the recommended dose.

Instructions for use

Your physician or pharmacist will show you how to use your inhaler. Not using the inhaler properly or not using as prescribed, may mean that the medicine will not help your asthma or COPD as it should.

The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.

Testing your 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 two puffs into the air. If you have not used the inhaler for a week or more, also release two puffs of medicine into the air.

Using your inhaler

It is important to start to breathe in 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 the 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 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. After use always replace the mouthpiece cover immediately to keep out

dust. Replace the cover by firmly pushing and snapping the cap into position.

Practice in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

If you or your child find it difficult to use Serevent Inhaler, it may be used with other devices to make its use easier e.g a spacer device. Talk to your physician or pharmacist for further advice.

Cleaning your inhaler

To stop your inhaler blocking up, 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.

Do not put the metal canister in water.

If you accidentally have inhaled a higher dosage

It is important to use the inhaler as instructed.

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

You may notice your heart beating faster than usual and that you feel shaky and/or dizzy. You may also have a headache, muscle weakness and aching joints.

If you forgot to take this medicine

If you forgot to inhale this medicine at the scheduled time, do not inhale a double dose to make up for the missed dose. Inhale the next dose at the

usual time and consult the physician.

Adhere to the treatment regimen recommended by your physician.

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

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

4. SIDE EFFECTS

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

To reduce the chances of side effects, your physician will prescribe the lowest dose of Serevent Inhaler needed to control your asthma or COPD. These are the side effects reported by people taking Serevent Inhaler:

Allergic reactions: you may notice your breathing suddenly gets worse after using Serevent Inhaler. 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 they happen suddenly after using Serevent Inhaler, **tell your physician straight away.** Allergic reactions to Serevent Inhaler are very rare (may affect up to 1 in 10,000 people).

Additional side effects

Common side effects

These may affect up to 1 in 10 people:

- Muscle cramps
- Feeling shaky, fast or uneven heartbeat (palpitations), headache, shaking hands (tremor). Tremors are more likely if you are taking more than two puffs twice daily. These side effects do not last long and happen less as treatment with Serevent Inhaler continues.

Uncommon side effects

These may affect up to 1 in 100 people:

- Rash
- Very fast heart rate (tachycardia). This is more likely to happen if you are taking more than two puffs twice daily
- Feeling nervous.

Rare side effects

These may affect up to 1 in 1,000 people:

- Feeling dizzy
- Being unable to sleep or finding sleep difficult
- A reduction in the amount of potassium in your blood (you may get an uneven heartbeat, muscle weakness, cramp).

Very rare side effects

These may affect up to 1 in 10,000 people:

- **Breathing difficulties or wheezing that gets worse straight after taking Serevent Inhaler.** If this happens, **stop using Serevent Inhaler.** Use a fast-acting 'reliever' inhaler to help your breathing and **tell your physician straight away**
- Uneven heartbeat or your heart gives an extra beat (arrhythmias). If this happens, do not stop using Serevent Inhaler but tell your physician
- 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
- Sore mouth or throat
- Feeling sick (nausea)
- Aching, swollen joints or chest pain.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this 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 closed 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.
- Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.
- Do not store above 30°C.
- The metal canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn it even if you think it is empty.

Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains: norflurane (HFA 134a).
- What the medicine looks like and the contents of the package:
Inhalation suspension in a sealed pressurised canister with a metering valve. The container is fitted into a plastic device incorporating a mouthpiece and a dust cap. One pressurised container contains 120 puffs.
- 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: 056-26-26922.

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