SEREVENT INHALER CFC-FREE

Patient Information Leaflet

SCHEDULING STATUS:

S4

SEREVENT INHALER CFC-FREE

Salmeterol xinafoate 25 µg (micrograms)

Metered-dose inhaler

Read all this leaflet carefully before you start using SEREVENT INHALER CFC-FREE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SEREVENT INHALER CFC-FREE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What SEREVENT INHALER CFC-FREE is and what it is used for

2. What you need to know before you use SEREVENT INHALER CFC-FREE

3. How to use SEREVENT INHALER CFC-FREE

4. Possible side effects

5. How to store SEREVENT INHALER CFC-FREE

6. Contents of the pack and other information.

1. What SEREVENT INHALER CFC-FREE is used for:

Salmeterol xinafoate is a bronchodilator. It relaxes the muscles in the walls of the small air passages in the lungs. Your doctor has prescribed SEREVENT INHALER CFC-FREE for you to treat your asthma, chronic bronchitis or emphysema.

2. What you need to know before you use SEREVENT INHALER CFC-FREE:

Do not use SEREVENT INHALER CFC-FREE:

- if you are allergic (hypersensitive) to salmeterol xinofoate, or to the any of the other ingredients in SEREVENT INHALER CFC-FREE
- if you have asthma and do not use a cortisone inhaler or tablets.
- if you are taking a medicine called ketoconazole, used to treat fungal infections.

Warnings and precautions:

Take special care with SEREVENT INHALER CFC-FREE:

Special care should be taken with SEREVENT INHALER CFC-FREE:

- if you are using SEREVENT INHALER CFC-FREE for your asthma, you must always use and continue taking any other asthma medication (e.g., a cortisone inhaler or cortisone tablets). Continue taking the same doses as before unless your doctor tells you otherwise. **Do not stop taking your cortisone inhaler or cortisone tablets when you start using SEREVENT INHALER CFC-FREE**
- if you have an overactive thyroid gland
- if you have a heart problem, or you are being treated for high blood pressure

- if you have been told you have low blood levels of potassium (hypokalaemia)
- if you have diabetes mellitus (sugar diabetes)

If your breathing or wheezing gets worse straight after using SEREVENT INHALER CFC-FREE, stop using it immediately and tell your doctor as soon as possible.

If the relief of your wheezing or chest tightness is not as good as usual or does not last for as long as usual, tell your doctor as soon as possible. Your chest condition may be getting worse and you may need an extra medicine.

Other medicines and SEREVENT INHALER CFC-FREE:

Always tell your healthcare professional if you are taking other medicines. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking the following medicines, before you start using your SEREVENT INHALER CFC-FREE:

- beta-blockers, such as atenolol and propranolol, used to treat high blood pressure
- ketoconazole (used to treat fungal infections).

Pregnancy and Breastfeeding and fertility:

You should not use SEREVENT INHALER CFC-FREE if you are pregnant. If you are using SEREVENT INHALER CFC-FREE you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using SEREVENT INHALER CFC-FREE.

3. How to use SEREVENT INHALER CFC-FREE:

Do not share medicines prescribed for you with any other person.

Always use SEREVENT INHALER CFC-FREE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

It is very important that you use your SEREVENT INHALER CFC-FREE regularly, every day.

The medicine in the SEREVENT INHALER CFC-FREE should be inhaled through your mouth into your lungs.

The usual dosage is:

- ***Adults:*** Two inhalations (2 x 25 micrograms of salmeterol) twice daily.
- ***Children 4 years and older:*** Two inhalations (2 x 25 micrograms of salmeterol) twice daily.
- SEREVENT is not recommended in children below 4 years of age.

Instructions on how to use your Inhaler:

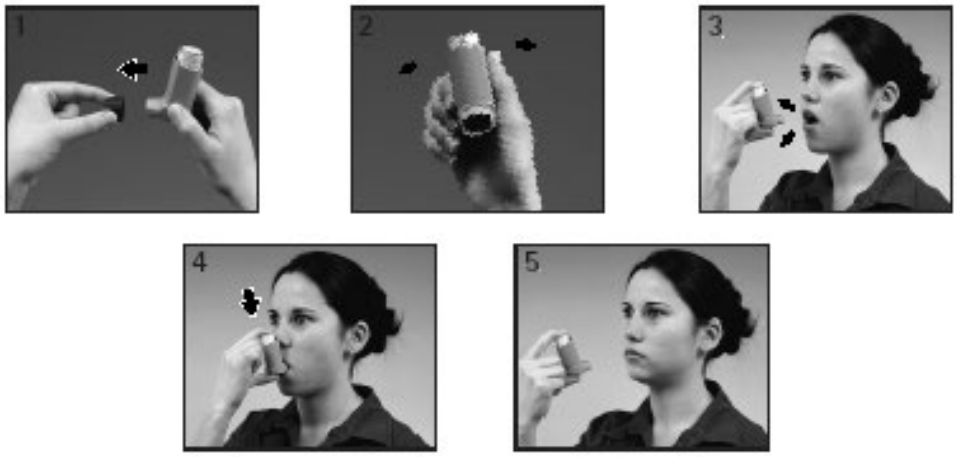
Testing your inhaler:

Before using a canister of SEREVENT INHALER CFC-FREE

for the first time, remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, hold the inhaler between fingers and thumb with your thumb at the base, below the mouthpiece and release puffs into the air to make sure that it works.

The inhaler should be shaken immediately before releasing each puff. If your inhaler has not been used for a week or more remove the mouthpiece cover, shake the inhaler well and release two puffs into the air.

Using your inhaler:



Using your inhaler:

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.
2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.
3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the inhaler upright between your fingers and thumb, with your thumb on the base, below the mouthpiece.
5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it, but do not bite it.
6. Just after starting to breathe in through your mouth, press firmly down on the top of the inhaler to release SEREVENT INHALER CFC-FREE, while still breathing in steadily and deeply.
7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.

8 To take the second inhalation, keep the inhaler upright and wait about half a minute before repeating steps 3 to 7.

9. Afterwards, rinse your mouth with water and spit it out.

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

Important:

Do not rush stages 5, 6 and 7. It is important that you start to breathe in as slowly as possible just before operating your inhaler. Practise in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth you should start again from stage 2.

If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties.

Cleaning:

Your inhaler should be cleaned at least once a week.

1. Remove the mouthpiece cover.
2. Do not remove the canister from the plastic casing.
3. Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth, tissue or cotton bud.
4. Replace the mouthpiece cover.

DO NOT PUT THE METAL CANISTER INTO WATER.

If you use more SEREVENT INHALER CFC-FREE than you should:

If you accidentally take a larger dose than recommended, you may notice that your heart is beating faster than usual and that you feel shaky. Other symptoms you may experience include headache, muscle weakness and aching joints.

In the event of overdosage, consult your doctor or pharmacist. If neither are available, contact the nearest hospital or poison control centre.

If you forget to use SEREVENT INHALER CFC-FREE:

If you miss a dose, just take the next dose when it is due. Do not use another dose of SEREVENT INHALER CFC-FREE to make up for a missed dose.

Effects when treatment with SEREVENT INHALER CFC-FREE is stopped:

It is important that you use your SEREVENT INHALER CFC-FREE regularly every day. Do not stop treatment even if you feel better, unless told to do so by your doctor.

If your breathing or wheezing gets worse straight after using SEREVENT INHALER CFC-FREE, stop using it immediately and tell your doctor as soon as possible.

If your shortness of breath and wheeze actually gets worse over several days, despite using SEREVENT INHALER CFC-FREE, or if you find you are increasing the use of your other inhaled medicines, tell your doctor immediately.

4. Possible side effects:

SEREVENT INHALER CFC-FREE can have side effects.

Not all side effects reported for SEREVENT INHALER CFC-FREE are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using SEREVENT INHALER CFC-FREE, please consult your doctor, pharmacist or other healthcare professional for advice.

SEREVENT INHALER CFC-FREE can cause allergic reactions. If any of the following happens, stop using SEREVENT INHALER CFC-FREE and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- skin rash (hives) or redness
- swelling around the face, mouth, lips, throat or tongue which may cause difficulty in swallowing
- becoming very wheezy, coughing or having difficulty in breathing
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness).

These are all very serious side effects. If you or your child have them, you may have had a very serious allergic reaction to SEREVENT INHALER CFC-FREE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- trembling or feeling shaky (tremor) and headache
- fast or uneven heartbeat (palpitations)
- muscle cramps

Less frequent side effects:

- rash
- rapid heartbeat (tachycardia)

Other side effects include:

- increases in the amounts of sugar in your blood (hyperglycaemia)

- **very fast heartbeat or chest pain**
- breathing difficulties or wheezing that gets worse straight after using SEREVENT INHALER CFC-FREE (paradoxical bronchospasm). Use your fast acting inhaler to help your breathing and tell your doctor immediately
- **joint pains (arthralgia).**

If any of these side effects get serious, please inform your doctor or pharmacist.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SEREVENT INHALER CFC-FREE.

5. How to store SEREVENT INHALER CFC-FREE:

Store all unused medicine out of reach of children.

Store at or below 30 ºC.

Protect from frost, heat and direct sunlight.

Replace the mouthpiece cover firmly and snap it into position.

Pressurised container: Do not expose to temperatures higher than 50 ºC. Do not puncture, break or burn the canister, even when apparently empty.

DO NOT PUT THE METAL CONTAINER IN WATER. Cross reference to the PI

Do not use after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information:

What SEREVENT INHALER CFC-FREE contains:

The active ingredient is salmeterol xinafoate.

Each actuation delivers 25 micrograms salmeterol (as xinafoate).

The other ingredient is chlorofluorocarbon (CFC)-free propellant norflurane (HFA 134_a).

What SEREVENT INHALER CFC-FREE looks like and contents of the pack:

SEREVENT INHALER CFC-FREE is a metered-dose aerosol inhaler comprising of a suspension of salmeterol xinafoate in a non-CFC propellant Norflurane.

The suspension is contained in an aluminium alloy can, internally coated with a specified fluoropolymer and sealed with a metering valve. Each canister is fitted with a plastic actuator incorporating an atomising nozzle and fitted with a dust-cap.

Canisters contain at least 120 actuations.

A single canister is packed into a carton.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

This leaflet was revised in:

23 January 2023

Registration number:

A40/10.2.1/0064

Date of first registration:

01 December 2006

GDS30

Trademarks are owned by or licensed to the GSK group of companies.

© 2023 GSK group of companies or its licensor