Package leaflet: Information for the patient

Salbutamol CFC Free 100 micrograms per metered dose Pressurised Inhalation, Suspension
salbutamol sulfate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Salbutamol CFC Free is and what it is used for
2. What you need to know before you use Salbutamol CFC Free
3. How to use Salbutamol CFC Free
4. Possible side effects
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1. What Salbutamol CFC Free is and what it is used for

Salbutamol CFC Free contains the active substance salbutamol sulfate. This belongs to a group of medicines called bronchodilators which help to relieve chest tightness and wheezing if you have asthma or another chest illness. Salbutamol acts directly upon the muscle in the airways of the lung causing the muscle to relax and the airways to open up.

Salbutamol is used to prevent or treat the symptoms of asthma, bronchitis and shortness of breath and coughing. Salbutamol CFC Free can be used regularly to control mild asthma or it may be used to treat occasional more severe asthma.

To help prevent attacks of asthma, Salbutamol CFC Free can also be used before exercise or before coming into contact with something that you know will bring on your asthma such as cat or dog fur.

Salbutamol CFC Free can be used in adults, adolescents and children 4 to 11 years of age.

Unlike salbutamol injection (and occasionally tablets), inhaled salbutamol cannot be used to treat premature labour or threatened miscarriage.

2. What you need to know before you use Salbutamol CFC Free

Do not use Salbutamol CFC Free:
- if you **or your child** are allergic to salbutamol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Salbutamol CFC Free:

- if you **or your child** suffer from an overactive thyroid (thyrotoxicosis).
- if you **or your child** have a history of heart disease, irregular heart rhythm or angina.
- if you **or your child** are being treated for high blood pressure.
- if you **or your child** have taken, or are taking, any medicines to control an irregular heartbeat/rhythm, including a very fast pulse.
- If you **or your child** have severe asthma as your doctor may need to carry out blood tests to monitor the amount of potassium in the blood).

During treatment
If you **or your child's** asthma gets worse, or if you notice that this medicine is less effective, talk to your doctor, as they may wish to check your **or your child's** lung function more closely or consider alternative treatment. If you have a **severe** wheezing attack and this medicine is not helping to relieve, seek medical advice **or go to your hospital immediately**.

Your doctor may also want to check levels of potassium in your blood, as salbutamol can affect this. If you have severe asthma, or need to use this medicine often, this maybe more likely to occur.

Children
Do not give this medicine to children under 4 years of age because other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

A RESPONSIBLE ADULT SHOULD SUPERVISE THE USE OF THE INHALER IN CHILDREN

Other medicines and Salbutamol CFC Free
Tell your doctor or pharmacist if you **or your child** are taking, have recently taken or might take any other medicines, in particular:
- medicines to reduce your blood pressure, such as beta-blockers (*e.g.* propranolol), guanethidine, reserpine and methyldopa.
- diuretics ('water tablets').
- steroids such as prednisolone (normally used for inflammation or to help calm the immune system).
- xanthine medicines such as theophylline or aminophylline.
- anti-depressants known as tricyclics (*e.g.* amitriptyline) or monoamine oxidase inhibitors (MAOIs).
- laxative medicines.

Anaesthetics
If you need an operation, including dental surgery, whilst using this medicine, tell the doctor, dentist or hospital staff that you are using this medicine. Salbutamol may interfere with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.

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 doctor or pharmacist for advice before using this medicine.

Salbutamol may affect the unborn baby or be present in the breast milk. Your doctor will decide with you whether or not you should use this medicine whilst pregnant or breast-feeding. Do not use without talking to your doctor first.

Driving and using machines
Salbutamol should not affect your ability to drive or operate machinery.

3. How to use Salbutamol CFC Free

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (including the elderly and adolescents aged 12 years and over)
The recommended dose is one puff of Salbutamol CFC Free to relieve an asthma attack. This may be increased to two puffs if required.

To prevent asthma attacks due to allergen exposure or exercise, two puffs of Salbutamol CFC Free are recommended before allergen exposure or exercise.

For regular treatment and to prevent attacks of asthma up to two puffs may be taken four times daily.

Use in children (over 4 years of age and less than 12 years of age)
The recommended dose is one puff of Salbutamol CFC Free to relieve an asthma attack or to prevent an asthma attack due to allergen exposure or before exercise. The dose may be increased to two puffs if required.

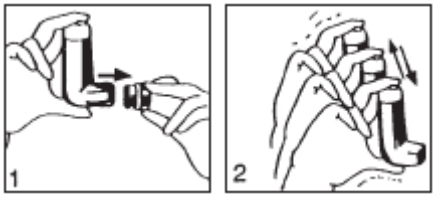
For regular treatment and to prevent attacks of asthma up to two puffs may be taken up to four times daily.

You or your child should not take more than 8 puffs in 24 hours and 2 puffs should not usually be taken more often than every 4 hours (up to a maximum total daily dose of 8 puffs only).

Other forms of this medicine may be more suitable for children under 4 years of age; ask your doctor or pharmacist.

Method of administration
Salbutamol CFC Free sprays a fine cloud of particles which you breathe in (inhale) through your mouth into your lungs. It is important that you know how to use your inhaler properly. Instructions on how to do this are given below. If you encounter any problems ask your doctor, nurse or pharmacist.

1. Remove the dust cap from the mouthpiece of the actuator (plastic case) by holding it between the thumb and forefinger and squeezing gently whilst pulling them apart. Check that there are no objects in the mouthpiece and that it is clean.
2. Hold the inhaler upright as shown in diagram 2 and shake well.



3. Breathe out slowly through your mouth until as far as is comfortable and then immediately place the mouthpiece of the actuator fully into your mouth between your teeth and close your lips lightly round it, but don't bite it.

4. Breathe in slowly and deeply and as you start to do so press the metal canister down firmly with your first finger to spray the aerosol and release the medicine. This action delivers a measured amount of salbutamol.
5. Relax the pressure on the metal canister. Continue to breathe in steadily and deeply.
6. Remove the mouthpiece of the actuator from your mouth while holding your breath for ten seconds or as long as comfortable, then breathe out slowly.
7. If your doctor instructs you to take a further puff, wait for about one minute, keeping the inhaler upright and then repeat steps 2 to 6.
8. Replace the dust cap on the mouthpiece by snapping it into place to protect the mouthpiece from dirt and dust.

Test Firing
Test the inhaler if it is new or has not been used for more than one week by shaking it well and firing two puffs into the air to check that it works.

If your Salbutamol CFC Free gets very cold, remove the metal canister from the actuator and warm it by rolling between your hands. DO NOT USE ANY OTHER SOURCE OF HEAT TO WARM IT UP.

Cleaning
Clean the inhaler once a week. To clean it:

1. Remove the metal canister by gripping it firmly and pulling it out of the actuator. Then remove the dust cap from the actuator.

2. Clean the mouthpiece of the actuator and dust cap in warm water. You can also add a mild detergent or baby bottle cleaning solution to the water, your pharmacist can advise you about this. If you use a cleaning solution rinse the actuator and dust cap in running water. DO NOT put the metal canister into water.

3. Dry the actuator and dust cap thoroughly inside and out. Avoid excessive direct heat.

Replace the dust cap and metal canister by reversing step 1.

Caution
The canister is pressurised – do not puncture or expose the canister to excessive heat even when empty.

If you or your child use more Salbutamol CFC Free than you should
Do not increase the dose of Salbutamol CFC Free unless your doctor tells you. If you do, you may suffer from side effects (see section 4, 'Possible side effects'). See your doctor at once if your condition gets worse or if you accidentally use a large amount of this medicine.

If you or your child forget to use Salbutamol CFC Free
If you forget to use Salbutamol CFC Free when you use it regularly, use it as soon as you remember and then space out the doses that you still have to take that day as much as possible. However, do not use the inhaler if it is almost time for your next regular dose.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you think you may have any of the following side effects, contact your doctor or go to your nearest hospital emergency room immediately:

Rare (may affect up to 1 in 1000 people):
- allergic reactions can occur which may appear as a rash or itching, swelling of the face, lips, mouth, tongue or throat, difficulty in breathing, dizziness, light headed or collapse

Very rare (may affect up to 1 in 10,000 people):
- sudden irregular or fast, racing heart beats

Not known (frequency cannot be estimated from the available data):
- chest pain (due to heart problems such as angina)

Other possible side effects:

Common (may affect up to 1 in 10 people):
- heart beating a little faster (tachycardia)

Uncommon (may affect up to 1 in 100 people):
- shaking, most noticeably of the hands
- heartbeats you feel like a thumping through your chest (palpitations)
- muscle cramps
- headache
- irritation of the mouth and throat

Rare (may affect up to 1 in 1,000 people):
- low levels of potassium in the blood
- increase in blood flow to your hands and feet causing them to be warmer than usual

Very rare (may affect up to 1 in 10,000 people):
- hyperactivity

Side effects in children and adolescents
In children and adolescents hyperactivity was seen more frequently than in adults.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 FREE Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salbutamol CFC Free

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after Expiry Date. The expiry date refers to the last day of that month.

- Do not store above 25°C. Protect from frost and direct sunlight.
- The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Salbutamol CFC Free contains
The active substance is salbutamol (as salbutamol sulfate)
Each metered dose of Salbutamol CFC Free contains salbutamol sulfate equivalent to salbutamol 100 micrograms
The other ingredients are oleic acid, norflurane (HFA 134a) and anhydrous ethanol.

What Salbutamol CFC Free looks like and contents of the pack
Your medicine is in the form of a pressurised inhalation aerosol.
Salbutamol CFC Free inhaler consists of a pressurised aluminium container closed with a metering valve containing a white or almost white suspension and a blue 'L' shaped plastic case with a removable dust cap at one end.
Each complete unit contains 200 metered doses.

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