

PACKAGE LEAFLET: INFORMATION FOR THE USER

Salamol® CFC-Free Inhaler 100 micrograms Pressurised Inhalation, Suspension (salbutamol sulphate)

Your medicine is available using the above name but will be referred to as Salamol CFC-Free Inhaler throughout this leaflet.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. **What Salamol CFC-Free Inhaler is and what it is used for**
2. **What you need to know before you use Salamol CFC-Free Inhaler**
3. **How to use Salamol CFC-Free Inhaler**
4. **Possible side effects**
5. **How to store Salamol CFC-Free Inhaler**
6. **Contents of the pack and other information**

1. WHAT SALAMOL CFC-FREE INHALER IS AND WHAT IT IS USED FOR
Salamol CFC-Free Inhaler contains a substance called salbutamol, which belongs to a class of medicines called bronchodilators.

Bronchodilators help manage **bronchospasm** (sudden narrowing of the tubes to the lungs caused by muscle spasm) by opening up the air passages in the lungs for up to 4 – 6 hours after administration.

Salamol CFC-Free Inhaler is used to treat:

- **asthma**
- **chronic obstructive pulmonary disease (COPD)**, such as chronic bronchitis and emphysema.

If you suffer from asthma, Salamol CFC-Free Inhaler can be used to both manage the symptoms before they occur and to relieve symptoms once they occur.

This type of medicine is known as a “reliever”. You may be using another medicine to prevent you from having an asthma attack (a “preventer”). You can safely use your preventer with your Salamol CFC-Free Inhaler.

Salamol CFC-Free Inhaler is for use in adults, adolescents and children (see section 3, “How to use Salamol CFC-Free Inhaler”).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SALAMOL CFC-FREE INHALER

Do NOT use Salamol CFC-Free Inhaler:

- if you are allergic to salbutamol or any of the other ingredients of this medicine (listed in section 6)
- for the general management of premature labour or threatened miscarriage. Although some forms of salbutamol can be used for such purposes, the inhaled salbutamol preparations such as Salamol CFC-Free Inhaler MUST NOT be used.

Special warnings and precautions

Talk to your doctor before you use Salamol CFC-Free Inhaler if you:

- suffer from **thyroid problems** due to excessive thyroid hormone (thyrotoxicosis)
- have a history of **heart disease**
- have **heart problems** such as poor blood flow to the heart (coronary insufficiency), high blood pressure (hypertension), severe heart failure, irregular heart rhythm (cardiac arrhythmias), or a fast heart rate
- have **diabetes**, as salbutamol may cause an increase in your blood sugar level
- suffer from **acute severe asthma**. Using this medicine may lead to low potassium levels in your blood, especially if you do not have enough oxygen in your blood (a condition called hypoxia). Your doctor may prescribe you regular blood tests to monitor your potassium levels. For medicines affecting potassium levels, see “Other medicines and Salamol CFC-Free Inhaler” in this section of the leaflet.

As severe asthma is a serious and potentially **life-threatening** condition, your doctor will regularly monitor your lung function and how well you are responding to treatment. Your doctor might also decide to prescribe you inhaled and/or oral corticosteroids (anti-inflammatory drugs).

If your intense breathing problems do not improve or get worse following the inhalation, you might need **urgent** medical attention (see section 4, “Possible side effects”).

If you are due to have **surgery** and/or **anaesthesia**, talk to your doctor or nurse (see “Other medicines and Salamol CFC-Free Inhaler”).

Children and adolescents

Salamol CFC-Free Inhaler is indicated for adolescents and children. An adult should always supervise children when they use Salamol CFC-Free Inhaler. Children may need help to use their inhaler. Parents can help by spraying the aerosol when the child begins to breathe in.

Other medicines and Salamol CFC-Free Inhaler

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

DO NOT use Salamol CFC-Free Inhaler if you are taking:

- propranolol or any other non-selective beta-blocking medicine (used to treat heart problems and high blood pressure).

Talk to your doctor if you are taking any of the following medicines.

The effects of salbutamol may be altered when used with:

- guanethidine and methyl dopa (medicines used to treat high blood pressure)
- reserpine (used to treat psychosis or high blood pressure)
- tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs), such as moclobemide (used to treat depression)
- digoxin (used to treat heart problems)
- disulfiram (used to treat chronic alcoholism)
- metronidazole, an antibiotic (used to treat infections).

Low potassium levels (hypokalaemia) may be worsened when salbutamol is used in particular with:

- xanthine derivatives, such as aminophylline or theophylline (used to improve breathing for people with asthma)
- glucocorticoids and other steroids (used to treat mainly inflammation and immune system disorders)
- diuretics, also known as “water tablets” (used to treat high blood pressure).

Caution should be exercised when using salbutamol with certain **anaesthetics** (such as chloroform, cyclopropane or halothane). Talk to your doctor or nurse if you are due to have a **surgery** and/or **anaesthesia** (see “Warnings and precautions”).

Talk to your doctor, pharmacist or nurse before taking any other medicine.

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 doctor for advice before taking/using any medicine.

During pregnancy, the use of Salamol CFC-Free Inhaler is NOT recommended, unless the expected benefit to the mother is greater than any possible risk to the baby.

When breast-feeding, the use of Salamol CFC-Free Inhaler is NOT recommended unless the expected benefit to the mother is greater than any possible risk to the baby. The medicine may pass into breast milk and have an effect on the baby.

There is no evidence of salbutamol affecting human fertility.

Salamol CFC-Free Inhaler contains ethanol (alcohol)

This medicinal product contains a small amount of ethanol (alcohol), less than 100mg per puff.

Driving and using machines

Salamol CFC-Free Inhaler is not expected to affect your ability to drive or operate machinery.

3. HOW TO USE SALAMOL CFC-FREE INHALER

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

The recommended dose is:

Adults (including elderly) and adolescents (children 12 years and over)

- **To relieve asthma:**
One or two puffs (100 or 200 micrograms).
- **To prevent asthma:**
Two puffs (200 micrograms) 10-15 minutes before exercise or exposure to a recognised allergen.
- **Long-term treatment:**
Up to two puffs (200 micrograms) 4 times a day.

Children under the age of 12 years

- **To relieve asthma:**
One puff (100 micrograms). Your doctor may increase this to two puffs (200 micrograms) if required.
- **To prevent asthma:**
One puff (100 micrograms) 10-15 minutes before exercise or exposure to a recognised allergen. Your doctor may increase this to two puffs if required.
- **Long-term treatment:**
Up to two puffs (200 micrograms) 4 times a day.

An adult should always supervise children when they use Salamol CFC-Free Inhaler. Children may need help to use their inhaler. Parents can help by spraying the aerosol when the child begins to breathe in.

All patients

- DO NOT take more than **eight puffs** in 24 hours.
- You should check with your doctor or pharmacist about when to use your inhaler and how many puffs you must use each day if you are not sure.
- If your usual treatment is not working or you need more than eight puffs per day, please **tell your doctor**. DO NOT increase your dose without consulting your doctor.

HOW TO USE YOUR INHALER

Before you use your inhaler, please read this leaflet carefully and follow the instructions.

You **MUST** clean your inhaler **once a week** to prevent blockage.

You should **sit or stand upright** while taking your dose. It is important when using your inhaler to hold it upright as your inhaler will not work if it is not held in this position.

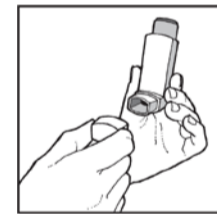
If your inhaler gets very cold, remove the metal can and warm it in your hand for a few minutes before you use it. Do NOT warm the can in any other way.

Testing your inhaler

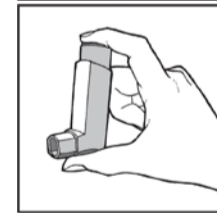
Test spray the inhaler by firing **two shots** into the air before you use it for the first time or if you have not used it for a period of **five days or more**.

Taking a dose

1. Take the cap off the inhaler. Make sure the mouthpiece is clean.



2. Hold the inhaler upright, with your thumb on the base and your first finger on the top of the can*. Now shake the inhaler vigorously up and down.



3. Breathe out normally as far as you comfortably can. Then hold the mouthpiece firmly between your lips.



4. Breathe in slowly and deeply. As you start to breathe in, press the aerosol can with your first finger to spray the aerosol and release the medicine. Continue to breathe in slowly and deeply.



5. Take the inhaler out of your mouth and hold your breath for 10 seconds, or as long as you comfortably can. Then breathe out slowly.



If you need more than one puff, wait about one minute and then start again from step 2. Put the cap back on the inhaler when finished.

IMPORTANT: Do NOT rush steps 3 and 4. It is important that you start to breathe in as slowly as possible just before using your inhaler. Practice in front of the mirror for the first few times. If you see “mist” coming from the top of the inhaler or the sides of your mouth, you should start again from step 2.

If your inhaler stops working properly

It is important to clean your inhaler **once a week** to prevent deposits from the aerosol building up and blocking the inhaler. If your inhaler seems not to be working, it may be that your inhaler has become blocked and you should clean your inhaler according to the section 'Cleaning your inhaler'.

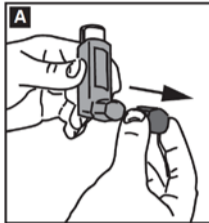
***Note:** Children and people with weak hands may find it easier to hold the inhaler with both hands; in this case, for step 2, put your two first fingers on the top of the can and both thumbs on the base of the inhaler.

* This product is compatible with the Volumatic® Spacer.

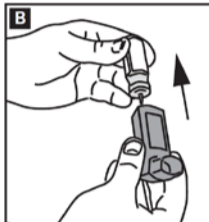
CLEANING YOUR INHALER

Keeping the plastic mouthpiece clean is very important as it will help prevent your inhaler becoming blocked. You must clean your inhaler **once a week**.

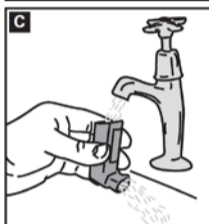
A. To clean your inhaler, first remove the mouthpiece cap.



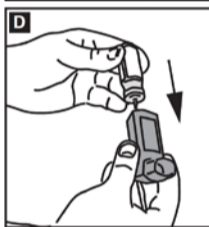
B. Remove the metal can from the plastic mouthpiece. DO NOT put the metal can into water.



C. Rinse the plastic mouthpiece and the mouthpiece cap with warm running water for at least 30 seconds.



D. Shake off any excess water and dry the plastic mouthpiece and mouthpiece cap thoroughly (leave to dry overnight if possible) but do NOT use direct heat. Put the metal can back in your inhaler. Replace the cap.



Failure to allow the mouthpiece to dry properly may result in your inhaler becoming blocked.

If you need to use your inhaler before it is dry

Shake off any water from the plastic mouthpiece and put the can back in. Test spray the inhaler by firing **two puffs** in the air before taking your usual dose. Wash and dry the mouthpiece again as described above.

If you use more Salamol CFC-Free Inhaler than you should

If you accidentally use more puffs than your doctor told you to, or if someone else uses the inhaler without prescription, please **contact your nearest hospital casualty department or tell your doctor immediately**.

Take this leaflet and the inhaler with you to the hospital or doctor so that they know what substance has been used. An overdose may cause side effects described in section 4 of this leaflet, especially muscle tremor, headache and fast heart beat.

If you forget to use Salamol CFC-Free Inhaler

If you forget to use your inhaler, take your recommended number of puffs when you remember, then carry on as before. DO NOT take a double dose to make up for a forgotten dose.

If you stop using Salamol CFC-Free Inhaler

DO NOT stop using your inhaler unless your doctor tells you to. If your doctor tells you to stop using your Salamol CFC-Free Inhaler, take any inhalers you have left back to your pharmacist.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Salamol CFC-Free Inhaler can cause side effects, although not everybody gets them.

STOP using Salamol CFC-Free Inhaler and tell your doctor or go to the casualty department at your nearest hospital IMMEDIATELY if:

- your breathing problems worsen or you experience wheezing following a dose of Salamol CFC-Free Inhaler
- you have signs of a **serious allergic reaction** (swelling of the lips, face or neck leading to severe difficulty in breathing; low blood pressure leading to collapse; skin rash or hives).

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or go to the casualty department at your nearest hospital IMMEDIATELY if you:

- suffer from heart disease and you experience chest pain, shortness of breath or any signs of your heart disease worsening
- have taken a dose of Salamol CFC-Free Inhaler and do not feel better after **3 hours** or longer.

Talk to your doctor, pharmacist or nurse if you experience any of the following side effects:

Common (affecting less than 1 in 10 patients):

- tremor
- headache
- heart rate that exceeds normal resting rate (tachycardia).

Uncommon (affecting less than 1 in 100 patients):

- palpitations
- mouth and throat irritation
- muscle cramps.

Rare (affecting less than 1 in 1,000 patients):

- low levels of potassium in the blood (hypokalaemia)
- flushing or redness of the face or skin, increased blood flow to your extremities (peripheral vasodilatation).

Very rare (affecting less than 1 in 10,000 patients):

- rapid and irregular heart beat (atrial fibrillation)
- rapid heart rhythm due to improper electrical activity of the heart (supraventricular tachycardia)
- premature electrical impulse in the heart, generated above the level of the heart chamber called ventricle (supraventricular extrasystoles)
- hyperactivity. In addition, children up to 12 years of age may experience the state of overexcitement, sleeping problems, and hallucinations.

Frequency not known:

- decreased blood flow to the parts of the heart, usually caused by narrowing or blocking of blood vessels (myocardial ischaemia).

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 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 SALAMOL CFC-FREE INHALER

- **Keep this medicine out of the sight and reach of children**
- If your inhaler gets very cold, remove the metal can and warm it in your hand for a few minutes before you use it. Do not warm the can in any other way.
- Do not store above 25°C. Do not refrigerate or freeze. Protect from frost, direct sunlight and heat.
- The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C.
- Do not pierce, break or burn the canister, even when apparently empty.
- Do not use this medicine after the expiry date (Exp) which is marked on the carton and label. This refers to the last day of that month.
- Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.
- If you have any left over/unused canisters or your doctor tells you to stop taking your medicine, please return these to your pharmacist for safe disposal.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Chlorofluorocarbons (CFCs) have been shown to damage the ozone layer in the atmosphere. Your Salamol CFC-Free Inhaler does not contain CFCs, instead the inhaler contains a hydrofluoroalkane (HFA-134a or norflurane) as an inactive ingredient. HFAs have been developed as a replacement for CFCs because they do not damage the ozone layer.

What Salamol CFC-Free Inhaler contains

- The active ingredient is salbutamol sulphate. Each actuation contains salbutamol sulphate equivalent to 100 micrograms salbutamol per metered dose.
- Your medicine also contains ethanol anhydrous (alcohol) and the propellant norflurane (propellant HFA-134a).

What Salamol CFC-Free Inhaler looks like and contents of the pack

- Salamol CFC-Free Inhaler is a pressurised container fitted with a metering valve and actuator. Each pack contains a single inhaler which supplies 200 metered doses.

Manufacturer

Manufactured by: IVAX Pharmaceuticals Ireland, Waterford, Ireland.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder:
Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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