

**PACKAGE LEAFLET: INFORMATION
FOR THE USER**

**Salamol Easi-Breathe® CFC-
Free Inhaler
100 micrograms Pressurised
Inhalation, Suspension
(salbutamol)**

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

- What Salamol Easi-Breathe CFC-Free Inhaler is and what it is used for
- Before you use Salamol Easi-Breathe CFC-Free Inhaler
- How to use Salamol Easi-Breathe CFC-Free Inhaler
- Possible side effects
- How to store Salamol Easi-Breathe CFC-Free Inhaler
- Further information

1. WHAT SALAMOL EASI-BREATHE CFC-FREE INHALER IS AND WHAT IT IS USED FOR

Salamol Easi-Breathe CFC-Free Inhaler is a bronchodilator and works by widening the airways in your lungs to allow air in and out. This helps you to feel less breathless, wheezy or tight-chested. Salamol Easi-Breathe CFC-Free Inhaler is used:

- to treat asthma
- to prevent asthma following exercise or induced by allergies
- for the relief of wheezing and shortness of breath caused by certain other chest diseases.

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 Easi-Breathe CFC-Free Inhaler.

2. BEFORE YOU USE SALAMOL EASI-BREATHE CFC-FREE INHALER

Do not use Salamol Easi-Breathe CFC-Free Inhaler

- Do not use your inhaler if you:
- are allergic (hypersensitive) to salbutamol or any of the other ingredients of this medicine.

Salamol Easi-Breathe CFC-Free Inhaler should NOT be used to treat premature labour or threatened miscarriage, as inhaled salbutamol products are not suitable for this purpose.

Take special care with Salamol Easi-Breathe CFC-Free Inhaler

Tell your doctor before you start to use your inhaler if you:

- have thyroid problems
- have a history of heart disease
- have heart problems (poor blood flow to the heart, high blood pressure, heart failure,

- irregular heart rhythm, angina or a fast heart rate)
- have severe asthma
- have diabetes.

Taking other medicines

Tell your doctor before you start to use your inhaler if you are taking:

- medicines used to treat high blood pressure known as beta-blockers (such as propranolol)
- medicines used to treat high blood pressure known as guanethidine and methyldopa
- reserpine (used to treat psychosis or high blood pressure)
- antidepressants known as monoamine oxidase inhibitors (MAOIs) such as moclobemide
- medicines for depression known as tricyclic antidepressants
- medicine used to treat heart problems known as digoxin
- medicines known as xanthines e.g. aminophylline or theophylline
- steroids
- water tablets (diuretics)
- laxatives.

Some anaesthetics may interfere with the effect of this inhaler.

If you see any other doctor or dentist, please tell them that you are using Salamol Easi-Breathe CFC-Free Inhaler.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription.

Pregnancy and breast-feeding

- If you are pregnant or are breast-feeding, do not use Salamol Easi-Breathe CFC-Free Inhaler unless your doctor has told you to do so.

Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Salamol Easi-Breathe CFC-Free Inhaler

- Salamol Easi-Breathe CFC-Free Inhaler contains a small amount of ethanol (alcohol).

3. HOW TO USE SALAMOL EASI-BREATHE CFC-FREE INHALER

Always use Salamol Easi-Breathe CFC-Free Inhaler exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You must use your inhaler as your doctor has told you to. The label will tell you how much to take and how often to take it.

The usual dose is:

Adults and Children (including the elderly)

- For the relief of symptoms such as wheezing and shortness of breath**

One puff for relief of an asthma attack. This may be increased to two puffs if necessary.

- For asthma due to exercise or allergies**

One puff 10 to 15 minutes before exercising or exposure to allergens. This may be increased to two puffs if necessary.

- For chronic therapy**

Two puffs up to four times a day. Four hours should be allowed between each dose.

An adult should always supervise children when they use Salamol Easi-Breathe 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

- If you have taken a dose of two puffs, then you should wait four hours before taking another dose. You should 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. You should not increase your dose without consulting your doctor.

HOW TO USE YOUR INHALER

You must remember to clean your inhaler once a week to prevent blockage.

You should sit or stand upright while taking your inhaler. 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.

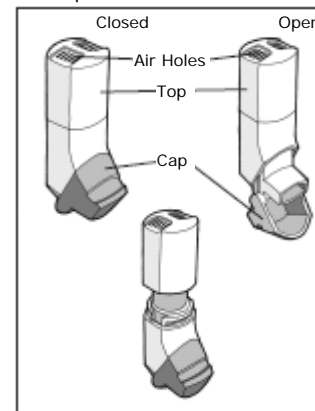
Salamol Easi-Breathe CFC-Free Inhaler is designed to make it easier for you to use. It is a breath-operated inhaler. This means it only releases a dose when you breathe in.

Important

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

Opening

To open the inhaler, fold down the cap which fits over the mouthpiece.

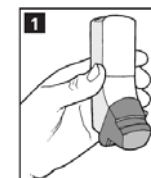


Test spray the inhaler by

firing two shots into the air before you use it for the first time and also if you have not used it for a period of five days or more.

To test spray your inhaler, unscrew the top of it so you can see the metal can inside. Open the cap, shake the inhaler and spray the aerosol by pressing the can with your finger or thumb. Close the cap and put the top back on.

- Shake the inhaler vigorously.



- Hold the inhaler upright and open it by folding down the cap which fits over the mouthpiece.

- Breathe out normally as far as you comfortably can. Then hold the mouthpiece firmly between your lips. Hold the inhaler upright and make sure that your hand is not blocking the airholes. Breathe in slowly and deeply through the mouthpiece. Don't stop breathing when the inhaler puffs the dose into your mouth. Carry on until you have taken a deep breath.

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



5. After you have used your inhaler, hold it upright and close the cap immediately.

6. If you need to take more than one puff, close the cap, wait about one minute and then start again from step 1.

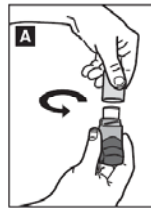
7. **You must keep your inhaler clean, especially in the mouthpiece. This will prevent deposits from the aerosol building up. To prevent your inhaler becoming blocked you must clean it once a week.**

8. What to do if your inhaler stops working properly

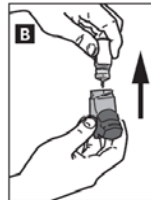
It is important to clean your inhaler regularly to prevent deposits from the aerosol building up and blocking the inhaler. If your inhaler seems not to be working, it may be that your inhaler has become blocked and you should clean your inhaler according to the section 'How to clean your inhaler'. In the unlikely event of the inhaler failing to operate correctly, the inhaler top can be unscrewed and the can pressed down. If your inhaler still does not work, return it to your doctor or pharmacist.

How to clean your inhaler

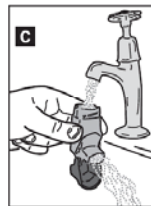
A Unscrew and remove the top of the inhaler. Keep this top dry at all times.



B Remove the metal can from the bottom of the inhaler. Do not put the metal can in water.



C Rinse the bottom of the inhaler with warm running water for at least 30 seconds.



D Shake off any excess water and dry the bottom of the inhaler thoroughly. Leave to dry overnight if possible, but do not use direct heat. Put the can back into the bottom of the inhaler. Close the cap and screw the top and bottom parts of your inhaler back together.

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 bottom of the inhaler and put the can back in. Test spray the inhaler by firing two puffs in the

air as previously described on Page 1. Screw the top and bottom parts of the inhaler together and take your usual dose. When you have taken your usual dose, wash and dry your inhaler again as described above.

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

If you accidentally take more puffs than your doctor told you to, please contact your nearest hospital casualty department or tell your doctor immediately. An overdose is likely to cause agitation and fast heart beat.

If you forget to use Salamol Easi-Breathe CFC-Free Inhaler

If you forget to use your inhaler, take your recommended number of puffs when you remember, then carry on as before. Never use more than your doctor has told you to.

If you stop using Salamol Easi-Breathe 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 Easi-Breathe 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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If, immediately after inhaling a puff, your asthma worsens, do not take any more puffs and contact your doctor straight away.

Stop using Salamol Easi-Breathe CFC-Free Inhaler and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an 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).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

If you suffer from heart disease, tell your doctor immediately or go to the casualty department at your nearest hospital if you experience the following while using Salamol Easi-Breathe CFC-Free Inhaler:

- chest pain or symptoms of your heart disease worsening.

The following side effects have been reported: Common (affecting more than one person in one hundred but fewer than one person in ten):

- tenseness (in the beginning of treatment)
- dizziness
- headache
- mild tremor (shaking).

Rare (affecting more than one person in ten thousand but fewer than one person in one thousand):

- throat irritation, mouth irritation or sore mouth
- being or feeling sick or vomiting
- muscle cramps
- tachycardia (fast heart rate) or palpitations
- hyperactivity in children
- low potassium levels or increased serum lactate levels in your blood. Your doctor may wish you to have regular blood tests to check your blood potassium levels.
- widening of blood vessels.

Very rare (affecting fewer than one person in ten thousand):

- trouble sleeping
- changes in the way the heart beats.

Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina).

If any of the side effects continue for more than a few days, get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SALAMOL EASI-BREATHE CFC-FREE INHALER

- Keep out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate or freeze. Protect from frost, direct sunlight and heat. 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.
- 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 after the expiry date (Exp) printed on the carton and label.
- If your medicine shows any signs of deterioration, please return this to your pharmacist who will advise you further.
- 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. FURTHER INFORMATION

Chlorofluorocarbons (CFCs) have been shown to damage the atmosphere. Your Salamol Easi-Breathe CFC-Free Inhaler does not contain CFCs, instead the inhaler contains a hydrofluoroalkane (called Norflurane) as an inactive ingredient. Hydrofluoroalkanes have been developed as a replacement for CFCs because they do not damage the ozone layer.

This information applies only to Salamol Easi-Breathe CFC-Free Inhaler.

What Salamol Easi-Breathe CFC-Free Inhaler contains

The name of your medicine is Salamol Easi-Breathe CFC-Free Inhaler 100 micrograms Pressurised Inhalation, Suspension.

The common name for your medicine is Salbutamol Sulphate.

Salamol Easi-Breathe CFC-Free Inhaler contains salbutamol sulphate, which is one of a group of medicines called beta agonists.

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). Norflurane has been developed to replace CFC propellants. Your inhaler does not contain CFCs. As Norflurane replaces the CFC propellant in your inhaler, YOU MAY NOTICE YOUR MEDICINE HAS A SOFTER, DRIER TASTE. This is due entirely to the change in propellants and has no effect on your medicine.

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

Salamol Easi-Breathe CFC-Free Inhaler contains at least 200 puffs.

Manufacturer

Your Salamol CFC-Free Inhaler is manufactured by: IVAX Pharmaceuticals Ireland, Waterford, Ireland.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2 North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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