

PACKAGE LEAFLET: INFORMATION FOR THE USER

Salamol Easi-Breathe[®] CFC-Free Inhaler 100 micrograms Pressurised Inhalation Suspension salbutamol (as 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, 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 Easi-Breathe is and what it is used for**
- 2. What you need to know before you use Salamol Easi-Breathe**
- 3. How to use Salamol Easi-Breathe**
- 4. Possible side effects**
- 5. How to store Salamol Easi-Breathe**
- 6. Contents of the pack and other information**

1. What Salamol Easi-Breathe is and what it is used for

Your medicine is called Salamol Easi-Breathe CFC-Free Inhaler (referred to as Salamol Easi-Breathe throughout this leaflet). It contains a medicine called salbutamol, which belongs to a group of medicines called fast-acting bronchodilators.

- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Salamol Easi-Breathe is used to treat:

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

If you suffer from asthma, Salamol Easi-Breathe 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 Easi-Breathe.

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

2. What you need to know before you use Salamol Easi-Breathe

Do NOT use Salamol Easi-Breathe:

- if you are allergic to salbutamol sulfate 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 Easi-Breathe MUST NOT be used.

Special warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Salamol Easi-Breathe if:

- you have high blood pressure
- you have an overactive thyroid gland
- you have a history of heart problems such as, severe heart failure, an irregular or fast heartbeat or angina.
- you have diabetes, as salbutamol may cause an increase in your blood sugar level
- you 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 Easi-Breathe” 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 Easi-Breathe”).

Children and adolescents

Salamol Easi-Breathe is indicated for adolescents and children.

An adult should always supervise children when they use Salamol Easi-Breathe. Children may need help to use their inhaler.

Other medicines and Salamol Easi-Breathe

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

Remember to take this medicine with you if you have to go to hospital.

In particular, tell your doctor, nurse or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat e.g. propranolol
- other medicines for your asthma
- medicines used to treat high blood pressure e.g. guanethidine and methyldopa
- reserpine (used to treat severe agitation 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:

- xantine 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”).

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 this medicine.

Salamol Easi-Breathe contains ethanol

This medicine contains 3.93 mg of alcohol (ethanol) in each metered dose. The amount in each metered dose of this medicine is equivalent to less than 0.1 ml beer or wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

Driving and using machines

Salamol Easi-Breathe is not expected to affect your ability to drive or operate machinery.

3. How to use Salamol Easi-Breathe

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

Salamol Easi-Breathe should be used as required rather than regularly.

If your asthma is active (for example you have frequent symptoms or flare ups, such as breathlessness that makes speaking, eating or sleeping difficult, cough, wheezing, tight chest or limited physical ability), you should tell your doctor right away who may start or increase a medicine to control your asthma such as an inhaled corticosteroid.

Tell your doctor as soon as possible if your medicine does not seem to be working as well as usual (for example you need higher doses to relieve your breathing problems or your inhaler fails to give relief for at least 3 hours) as your asthma may be getting worse and you may need a different medicine.

If you use Salamol Easi-Breathe more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

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 Easi-Breathe. Children may need help to use their inhaler.

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.

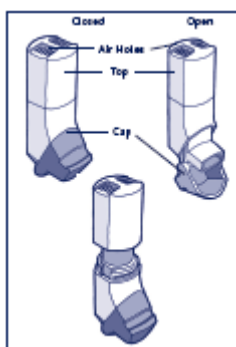
You should **sit or stand upright** while taking your dose. It is important when using your inhaler to hold it upright as your inhaler will not work if it is not held in this position.

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.

Salamol Easi-Breathe 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.

Opening

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



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**.

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.

Taking a dose

1. Shake the inhaler vigorously.



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



3. 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. Do NOT 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**.

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

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'.

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.

Cleaning your inhaler

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



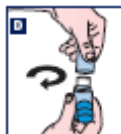
2. Remove the metal can from the bottom of the inhaler. DO NOT put the metal can in water.



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



4. 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 in section “Testing your inhaler”. 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 take more Salamol Easi-Breathe than you should

If you take more than you should, talk to a doctor as soon as possible.

The following effects may happen:

- your heart beats faster than usual
- you feel shaky
- hyperactivity
- acid builds up in your body which may cause your breathing to become faster.

These effects usually wear off in a few hours.

If you forget to take Salamol Easi-Breathe

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Salamol Easi-Breathe

Do not stop taking Salamol Easi-Breathe without talking to your doctor.

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

4. Possible side effects

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

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

STOP using Salamol Easi-Breathe 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 Easi-Breathe
- 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 Easi-Breathe and do not feel better after **3 hours** or longer.

Talk to your doctor as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these affect less than 1 in 10 people.

If any of these happen to you, talk to your doctor as soon as possible. Do not stop using this medicine unless told to do so.

Tell your doctor if you have any of the following side effects which may also happen with this medicine:

Common (affecting less than 1 in 10 people):

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

Uncommon (affecting less than 1 in 100 people):

- palpitations
- mouth and throat irritation
- muscle cramps.

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

- a low level of potassium in your 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 people):

- 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)
- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.
- hyperactivity. In addition, children up to 12 years of age may experience the state of overexcitement, sleeping problems, and hallucinations.

The following side effects can also happen but the frequency of these are not known:

- decreased blood flow to the parts of the heart, usually caused by narrowing or blocking of blood vessels (myocardial ischaemia).
- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

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 HPRAs Pharmacovigilance Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra doses of Salamol Easi-Breathe unless your doctor tells you to.

5. How to store Salamol Easi-Breathe

Keep all medicines out of the sight and reach of children.

Do not store above 25°C. Do not refrigerate or freeze.

Pressurised aerosol can. Do not puncture, break or burn the can, even if it seems empty.

Do not expose to temperatures higher than 50°C.

Do not use your inhaler after the expiry date stamped on the label. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information**What Salamol Easi-Breathe contains**

- The active ingredient is salbutamol sulfate. Each metered dose (“puff”) contains equivalent of 100 micrograms of salbutamol.
- The other ingredients are ethanol anhydrous (alcohol) and norflurane (hydroflouroalkane, HFA-134a).

Salamol Easi-Breathe does not contain CFCs. This means that your Inhaler does not use CFCs to spray the medicine. The propellant used in your inhaler is a hydrofluoroalkane (HFA-134a). HFA-134a does not damage the ozone layer, unlike CFCs.

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

The can is of 14 ml brimful capacity, manufactured from deep drawn aluminium with either a debossed or plain base, and is supplied with a metering valve of 25 microlitres and breath-operated actuator. Each inhaler supplies a minimum of 200 metered doses.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in January 2024.