

Salamol Easi-Breathe® CFC-Free Inhaler
100 micrograms Pressurised Inhalation Suspension
 Salbutamol Sulfate
 Package leaflet: Information for the patient



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

Effect

Salamol Easi-Breathe® contains salbutamol sulfate, which belongs to a group of medicines called beta agonists. Salbutamol 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.

Usage

Salamol Easi-Breathe® is used to treat asthma in adults, adolescents and children aged 4 to 11 years. It can also be used to prevent asthma caused by exercise or asthma caused by a reaction to allergens (substances to which you are allergic to e.g. house dust, pollen, dog hair, cat hair, cigarette smoke, etc.) or to treat breathing difficulties associated with reversible airways obstruction (e.g. chronic obstructive pulmonary disease [COPD]). This type of medicine is known as a 'reliever'. You may be using another medicine to prevent you from having an asthma attack ('controller medication'). You can safely use your controller medication with this medicine.

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

Do not use Salamol Easi-Breathe®

- if you are allergic to salbutamol or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Salamol Easi-Breathe®

- if you suffer from thyroid problems, diabetes, serious heart disease, fast irregular heart rhythms or high blood pressure.

- if you have a condition known as hypoxia (a disorder where the oxygen level in the blood is low and may cause breathlessness) or if you have a history of heart disease or angina.

Consult a doctor immediately if your usual treatment is not working or you need more than 8 puffs per day (for adults) or 4 puffs per day (for children) or in case of worsening asthma symptoms. Your dosage should only be increased on medical advice.

Other medicines and Salamol Easi-Breathe®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are having treatment that requires a general anaesthetic, please tell your anaesthetist that you are taking Salamol Easi-Breathe®. Do not use this medicine for at least six hours before the intended anaesthetic.

Salbutamol can reduce the amount of potassium in your blood. If this happens, you may notice an irregular heartbeat, muscle weakness or cramp.

This is more likely to happen if you use salbutamol with some medicines used to treat high blood pressure, other medicines used to treat breathing problems (e.g. steroids), stimulants (e.g. xanthines) and long-term laxatives.

The following medicines may influence the effect of Salamol Easi-Breathe®:

- Some medicines for the treatment of high blood pressure such as beta-blockers (e.g. propranolol);
- Medicines used to treat heart disease (e.g. digoxin);
- Medicines for the treatment of depression (from the monoamine oxidase inhibitor group e.g. phenelzine or tricyclic antidepressants e.g. amitriptyline or trazodone);
- Water tablets (diuretics);
- Medicines for the treatment of chronic alcoholism (e.g. disulfiram);
- The anti-microbial drug metronidazole.

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 taking this medicine.

Driving and using machines

Salamol Easi-Breathe® does not affect the ability to drive or to use machinery.

3. How to use Salamol Easi-Breathe®

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

The dosage is individually adjusted according to your doctor's instructions, based on previous asthma therapy.

For the best results with this medicine you should use it when required to relieve symptoms of asthma and other chest conditions with similar symptoms, such as wheezing, breathlessness and tightness in your chest. Take one puff as a starting dose. This may be increased to two puffs if necessary.

To prevent asthma caused by exercise or allergens (e.g. house dust, pollen etc.), take two puffs 10-15 minutes before you exercise or before exposure to known allergens.

Do not take more than eight puffs in 24 hours. Wait 4 hours between doses.

Use in children and adolescents

The usual dose for children under the age of 12 years to relieve asthma symptoms such as wheezing, breathlessness and tightness in your chest, take one puff as a starting dose. This may be increased to two puffs if necessary.

Children over the age of 12 should refer to the adult dosage instructions above.

The usual dose for children under the age of 12 years to prevent asthma caused by exercise or allergens (e.g. house dust, pollen etc.), is one puff 10-15 minutes before exercise or before exposure to known allergens. This can be increased to two puffs if necessary.

Children over the age of 12 should refer to the adult dosage instructions above.

The usual dose for children under the age of 12 years for regular treatment of asthma is up to 2 puffs, 4 times a day.

Do not take more than eight puffs in 24 hours. Wait 4 hours between doses.

Instructions for use Important

Before using this medicine, please read this leaflet carefully and follow the instructions.

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

Always remember the following:

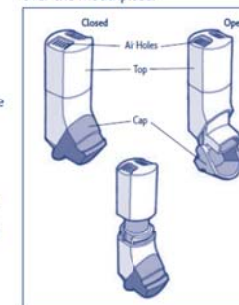
- Wait four hours between doses.
- Tell your doctor if your asthma gets worse or if this medicine does not provide as much relief from your asthma as before.
- You should sit or stand upright while taking this medicine. It is important when using this medicine to hold the inhaler upright as it will not work if it is not held in this position.

This 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.

Using the Inhaler

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.

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. 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.



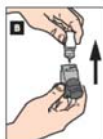
7. What to do if your inhaler stops working properly? If your inhaler does not work properly, unscrew the top and press the can down. It is important to clean your inhaler regularly to prevent deposits from the aerosol building up and blocking the inhaler. If your inhaler does not seem to be working, it may be that your inhaler has become blocked and you should clean your inhaler as detailed below. If your inhaler still does not work, return it to your doctor or pharmacist.

Cleaning the inhaler

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.



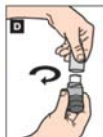
A To clean your inhaler unscrew and remove the top of the inhaler. Keep this top dry at all times.



B Remove the metal can from the bottom of the inhaler. Do not put the metal can into 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 will result in an increase in blockage problems.

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 above. Screw the top and bottom parts of your 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® than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you accidentally take a larger dose than recommended, you may notice that your heart is beating faster than usual, that you feel shaky or tense, you may have a headache and your skin may look flushed and feel hot. These effects usually wear off in a few hours, but you should tell your doctor as soon as possible. Your doctor may want to check your blood potassium levels.

4. Possible side effects

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

Contact your doctor immediately if you experience allergic (hypersensitivity) reactions. These include

- Wheezing, coughing and difficulty in breathing;
- Rash, swelling of the face and throat, and a fall in blood pressure

If you experience any of these side effects or if they occur suddenly after using salbutamol you should stop using your medication straightaway and tell your doctor immediately. Allergic reactions to salbutamol are very rare (occurring in less than 1 in 10,000 patients).

Other side effects:

Common (may affect up to 1 in 10 people):

- Feeling tense and getting headaches (which are more likely with higher doses);
- Feeling shaky (muscle tremors);
- Dizziness.

Uncommon (may affect up to 1 in 100 people):

- Muscle pain (myalgia).

Rare (may affect up to 1 in 1,000 people):

- Reduction in the amount of potassium in your blood (if this happens, you may notice an irregular heartbeat, muscle weakness or cramp);

- Increase in lactate levels and acid levels in the blood (you may experience symptoms such as persistent nausea and vomiting, unexplained tiredness, shortness of breath and rapid breathing, cold or blue hands and feet);
- Sleep disturbances and sensing things that are not real;
- Rapid or irregular heart beat (tachycardia or palpitations);
- Increased blood flow to your extremities (peripheral dilatation)
- Mouth and throat irritations; nausea, vomiting and dry and sore mouth;
- Muscle cramps.

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

- Difficulty in sleeping (insomnia);
- Itching of your skin;
- Trembling (particularly your hands).

Not known (frequency cannot be estimated from the available data):

- Chest pain (due to heart problems such as angina).

Additional side effects in children

You might collapse in very rare circumstances.

- Sleep disturbances and sensing things that are not real have been reported.
- Hyperactivity.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salamol Easi-Breathe®

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 and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate or freeze. If this medicine gets very cold, remove the metal can from the inhaler and warm it in your hands for a few minutes before you use it. Do not warm the can in any other way. Pressurised aerosol can. Do not puncture, break or burn the can, even if it seems empty.

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 Salamol Easi-Breathe® contains

- The active substance is salbutamol sulfate equivalent to 100 micrograms of salbutamol in each puff (metered dose).
- The other ingredients are ethanol anhydrous (alcohol) and the propellant norflurane (HFA-134a). This medicine does not contain any CFCs.

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

- The name of your medicine is Salamol Easi-Breathe® CFC-Free Inhaler 100 micrograms Pressurised Inhalation Suspension.
- Each pack of Salamol Easi-Breathe® contains a single inhaler and can which supplies 200 metered doses.

Marketing Authorisation Holder:

Norton Healthcare Ltd,
T/A IVAX Pharmaceuticals UK,
Ridings Point,
Whistler Drive,
Castletford,
West Yorkshire,
WF10 5HX,
United Kingdom

Manufacturer:

IVAX Pharmaceuticals Ireland,
IDA Industrial Park,
Waterford,
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Salamol Easi-Breathe® CFC-Free Inhaler 100 micrograms Pressurised Inhalation Suspension.

Germany: Salbulair N 100 mikrogramme Easi-Breathe Druckgasinhalation, Suspension.

The Netherlands: Salbutamol 100 Redihaler 100 microgram/dosis aerosol, suspensie.

Denmark: Salamol.

This leaflet was last revised in 03/2016

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