

Salamol Easi-Breathe® 100 micrograms/actuation Inhaler

(salbutamol sulphate)

This medicine is available using the above name but will be referred to as Salamol Easi-Breathe throughout this leaflet.

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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Effect

Salamol Easi-Breathe contains salbutamol sulphate, 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. 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. Before you use Salamol Easi-Breathe

Do not use Salamol Easi-Breathe

- If you are allergic to salbutamol (active ingredient) or any of the other ingredients in this medicine.

Take special care with Salamol Easi-Breathe

Let your doctor know if you suffer from thyroid problems, diabetes, serious heart disease, fast irregular heart rhythms or high blood pressure. Tell your doctor 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.

Taking other medicines

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

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

Ask your doctor or pharmacist for advice before taking any medicine. Salamol Easi-Breathe should only be used if recommended by a doctor.

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 has told you to. You should 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. The usual dose for Salamol Easi-Breathe is:

Adults and the elderly:

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.

Children:

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.

To prevent asthma caused by exercise or allergens (e.g. house dust, pollen etc.), take one puff 10-15 minutes before you exercise or before exposure to known allergens. This can be increased to two puffs if necessary.

Do not take more than four 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:

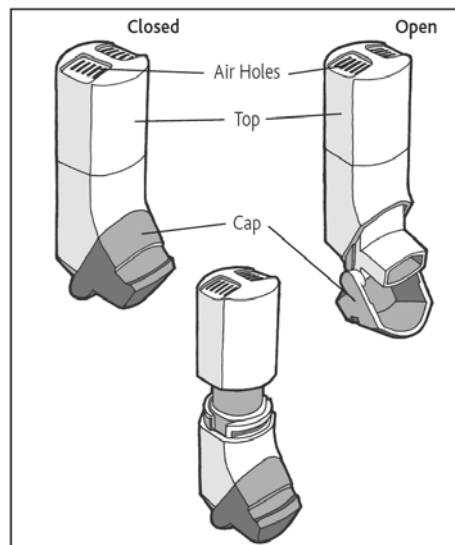
- Wait four hours between doses.
- Tell your doctor if your asthma gets worse or if this medicine does not provide as much relief from your asthma as before.
- You should sit or stand upright while taking this medicine. It is important when using this medicine to hold the inhaler upright as it will not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

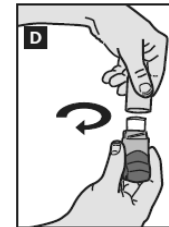
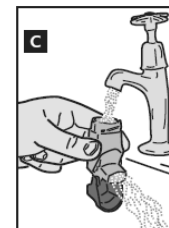
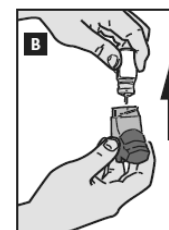
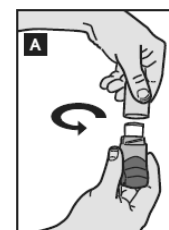
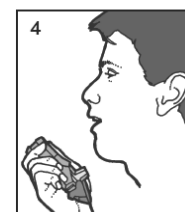
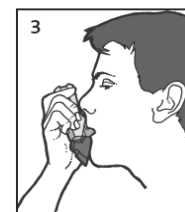
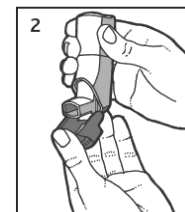
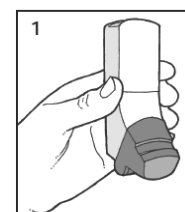
B. Remove the metal can from the bottom of the inhaler. Do not put the metal can into water.

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 Salamol Easi-Breathe 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 (less than 1 in 10 patients, but more than 1 in 100):

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

Uncommon (less than 1 in 100 patients, but more than 1 in 1,000):

- Muscle pain (myalgia).

Rare (less than 1 in 1,000, but more than 1 in 10,000):

- 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 (less than 1 in 10,000):

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

Not known:

- 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.

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, but do not stop using this medicine unless you are told to do so.

5. How to store Salamol Easi-Breathe

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not refrigerate or freeze. Protect from heat.

If this medicine gets very cold, remove the canister 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 container. Do not pierce or burn container even when empty.

Do not use this medicine after the expiry date which is stated on the label and carton.

If your inhaler fails to work properly or shows any signs of deterioration, you should seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. FURTHER INFORMATION

What Salamol Easi-Breathe contains

- The active substance is salbutamol sulphate.
Each actuation contains 100 micrograms salbutamol (as salbutamol sulphate).
The other ingredients are ethanol anhydrous and the propellant norflurane. This medicine does not contain any CFCs.

What Qvar Easi-Breathe Inhaler looks like and contents of the pack:

A pressurised metal canister enclosed in a blue plastic casing with a dark blue cap.

Each pack contains single Inhaler which supplies 200 actuations.

Product Licence Holder and Manufacturer

Manufactured by

Norton Waterford (IVAX Pharmaceuticals Ireland), Waterford, Ireland.

Teva Czech Industries s.r.o., Opava-Komarov, Czech Republic.

Procured from within the EU by Product Licence holder
Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex,
HA1 1XD. Repackaged by Servipharm Ltd.

POM

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