

Patient information leaflet
Salamol CFC-Free Inhaler 100micrograms
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.

The name of your medicine is Salamol CFC-Free Inhaler 100micrograms Pressurised Inhalation, Suspension but will be referred to as Salamol throughout this leaflet.

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1. WHAT SALAMOL IS AND WHAT IT IS USED FOR

Salamol contains a medicine called salbutamol. This belongs to a group of medicines called 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 is used to help prevent and treat breathing problems in people with asthma and chronic obstructive airways disease.

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.

Salamol is for use in adults, adolescents and children.

2. BEFORE YOU USE SALAMOL

Do not use Salamol

Do not use your inhaler if you:

- are allergic (hypersensitive) to salbutamol or any of the other ingredients of this medicine.

Salamol 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

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.

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 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

- Salamol contains a small amount of ethanol (alcohol), less than 100mg per puff.

3. HOW TO USE SALAMOL

Always use Salamol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and Adolescents (children 12 years and over)

To relieve asthma

One or two puffs (100 or 200micrograms).

To prevent asthma

Two puffs (200micrograms) 10-15 minutes before exercise or exposure to a recognised allergen.

Long term treatment

Up to two puffs (200micrograms) 4 times a day.

Children under the age of 12 years

To relieve asthma

One puff (100micrograms). Your doctor may increase this to two puffs (200micrograms) if required.

To prevent asthma

One puff (100micrograms) 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 (200micrograms) 4 times a day.

The maximum dose is 8 puffs (800micrograms) in a 24 hour period.

An adult should always supervise children when they use Salamol. 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.

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.

1. Take the cap off the inhaler. Make sure the mouthpiece is clean and clear of fluff and dirt.



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. At the same time 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. Breathe out slowly.



6. 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.

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'.

If your inhaler still does not work, return it to your doctor or pharmacist.

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.

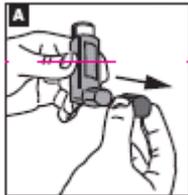
* **Note:** Children and people with weak hands may find it easier to hold the inhaler with both hands, in this case for step 2 put your two first fingers on the top of the can and both thumbs on the base of the inhaler.

This product is compatible with the Volumatic® Spacer.

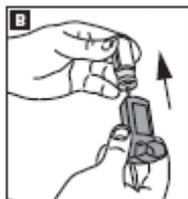
HOW TO CLEAN YOUR INHALER

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.

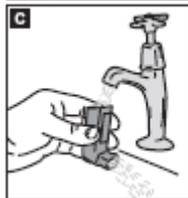
- A. To clean your inhaler, first remove the mouthpiece cap.



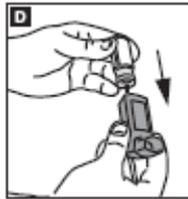
- B. Remove the metal can from the plastic mouthpiece. Do not put the metal can into water.



- 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 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

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

Do not stop using your inhaler unless your doctor tells you to. If your doctor tells you to stop using your Salamol, 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 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 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 :

- 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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5. HOW TO STORE SALAMOL

• KEEP 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.
- Pressurised aerosol can, do not expose to temperatures higher than 50°C. Do not puncture break or burn the can, even if it seems empty.
- Don't use your inhaler after the expiry date stamped on the outer carton and canister labels.

6. FURTHER INFORMATION

What Salamol contains

Salamol delivers salbutamol sulphate equivalent to 100micrograms of salbutamol in each puff (metered actuation). 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.

Contents of pack

Each pack of Salamol contains at least 200 puffs.

Manufactured by: IVAX Pharmaceuticals Ireland, Waterford, Ireland.

Procured from within the EU and repackaged by PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK

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PPA No: 1328/40/1

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