

Package Leaflet: Information for the User

Asthalin 100 micrograms Inhaler

Salbutamol Sulphate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

The full name of this product is Salbutamol Sulphate 100 micrograms Inhaler. However, this name will be shortened within the text of this leaflet to Salbutamol Sulphate Inhaler.

- 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 **Salbutamol Sulphate Inhaler** is and what it is used for
2. What you need to know before you use **Salbutamol Sulphate Inhaler**
3. How to use **Salbutamol Sulphate Inhaler**
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1. What Salbutamol Sulphate Inhaler is and what it is used for

Salbutamol Sulphate Inhaler is a pressurised inhalation suspension (inhaler) which contains the active ingredient salbutamol (as salbutamol sulphate). Salbutamol 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.

Salbutamol Sulphate Inhaler is used:

- to treat breathing problems in people with asthma and similar conditions
- to prevent asthma following exercise or other “triggers” (These are things, which bring on asthma symptoms in some people. Common triggers include house dust, pollen, cats, dogs and cigarette smoke)

Salbutamol Sulphate Inhaler cannot be used with any spacing device at this time. If you need a spacing device, your doctor will need to prescribe another product, which can be used with a spacing device, instead of Salbutamol Sulphate Inhaler.

Salbutamol Sulphate Inhaler contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Salbutamol Sulphate Inhaler. This will make no difference to how your medicine works.

2. What you need to know before you use Salbutamol Sulphate Inhaler

Do not use Salbutamol Sulphate Inhaler:

- if you are allergic to salbutamol sulphate or any of the other ingredients of this medicine (listed in section 6)
- in premature labour or have a threatened miscarriage.

Warnings and precautions

Salbutamol Sulphate Inhaler should be used as required rather than regularly.

Talk to your doctor, pharmacist or nurse before using this medicine 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). Your doctor right away may start or increase a medicine to control your asthma such as an inhaled corticosteroid.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you have overactive thyroid gland
- you have a history of or have serious heart disease or angina.
- have hypoxia (a lack of oxygen in the body)
- you have diabetes
- you suffer from fast irregular heart rhythms or have high blood pressure
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.

All patients

Consult a doctor immediately if your usual treatment is not working or if you need more than 8 puffs per day (adult) or 4 puffs per day (children) or in case of worsening asthma symptoms.

Your dose or frequency should only be increased on medical advice.

Other medicines and Salbutamol Sulphate Inhaler

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

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

- xanthines e.g. aminophylline or theophylline
- disulfiram
- water tablets (diuretics)
- beta-blockers e. g. propranolol
- monoamine oxidase-inhibitors (anti-depressants) e. g. phenelzine
- metronidazole
- steroids
- long-term laxatives
- medicines used to treat heart disease e. g. digoxin
- tricyclic antidepressants e. g. amitriptyline or trazodone

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

Salbutamol Sulphate Inhaler with food and drink

You can take Salbutamol Sulphate Inhaler at any time of day, with or without food.

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, nurse or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine may cause dizziness. If you are affected, DO NOT drive or operate machinery.

Salbutamol Sulphate Inhaler contains ethanol

This medicine contains a small amount of ethanol (alcohol)

3. How to use Salbutamol Sulphate Inhaler

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

The recommended dose is:

Adults and adolescents aged 12 years and over

- For the relief of symptoms such as wheezing and shortness of breath - Either one or two puffs as needed.
- For preventing asthma - Two puffs before exercising 10-15 minutes before exercise or exposure to a “trigger”
- For regular treatment - Two puffs up to 4 times a day

Children (aged 4 to 11 years)

- For the relief of symptoms such as wheezing and shortness of breath - Usually one puff. This may be increased to two puffs if necessary.
- For preventing asthma - Usually one puff before exercising. This may be increased to two puffs if necessary.
- For chronic therapy - Usually up to two puffs four times daily

Children (aged 12 years and over)

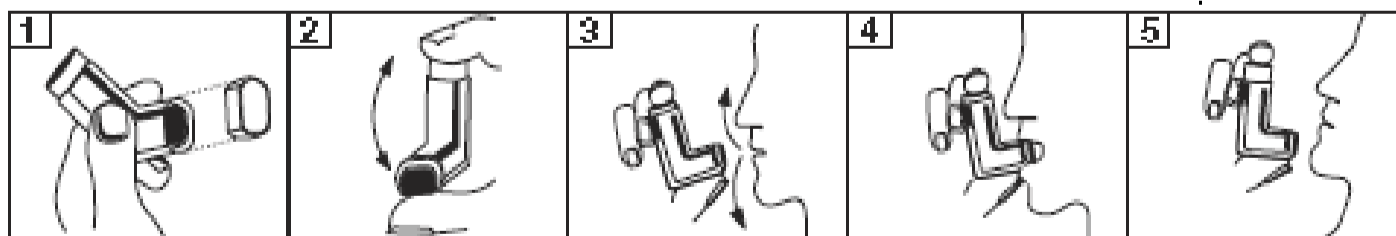
Dose as per adult population

Children using this inhaler should be supervised by an adult and should use this inhaler only as advised by the doctor.

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:



1. If your inhaler is new, or if you have not used your inhaler for a week or more, shake well, remove the mouthpiece cover and release two sprays into the air before using.
2. Remove the mouthpiece cover and check that the inside and outside of the mouthpiece is clear of dust, dirt or foreign objects (figure 1).
3. If the inhaler is very cold, the canister should be taken out of the plastic actuator and warmed in your hands for a few minutes before you use it. Do not use anything else to warm the canister. Shake the inhaler before each use (figure 2).
4. Hold the inhaler upright with a thumb on the base. Breathe out as far as is comfortable (it is important that you practice this before using the inhaler – see “Breathing technique” (figure 3).
5. and then immediately place the mouthpiece in your mouth and close your lips around it (figure 4). Be careful not to bite the mouthpiece.

6. Breathe in slowly through your mouth. Just after starting to breathe in through your mouth, press firmly down on the top of the inhaler to release an actuation (puff). Carry on breathing in deeply and steadily (figure 4).
7. Hold your breath, take the inhaler from your mouth and take your finger away from the top of the inhaler. Continue holding your breath for about 10 seconds, or for as long as is comfortable (figure 5). Then breathe out slowly.
8. If you are taking another puff, keep the inhaler upright and wait for at least 30 seconds before repeating steps 3 – 7.
9. After use, replace the mouthpiece cover firmly, making sure it snaps into position.

Breathing technique

You must breathe in as slowly as possible just before using the inhaler. Do not rush steps 5 to 7. You should practice a few times in front of a mirror. If you see “mist” coming from the inhaler or the sides of your mouth, then you need to start again from step 3.

People with weak hands may find it easier to hold the inhaler with two hands, with the two forefingers on the top of the inhaler and both thumbs on the bottom under the mouthpiece.

Cleaning your inhaler

You should follow the cleaning instructions described below very carefully in order to ensure that your inhaler continues to work properly.

Clean your inhaler once a week, or if blocked.

1. First remove the metal can from the plastic actuator and take off the mouthpiece cover.
2. Rinse the plastic actuator, mouthpiece and mouthpiece cover in tap water. DO NOT place the metal can into water or clean the can using water. Make sure the water runs through the actuator from both ends to ensure that the actuator orifice (the small hole that can be seen through the mouthpiece) is clear and not blocked.
3. The plastic components (actuator and mouthpiece cover) should be placed in a warm place to dry thoroughly before putting the inhaler back together. Avoid drying near direct or excessive heat.

If you use more Salbutamol Sulphate 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. You may notice that your heart is beating faster than usual, that you feel shaky or tense, you may have a headache or your skin may look flushed and feel hot. These effects normally wear off in a few hours. Your doctor may want to check your blood potassium levels.

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

4. Possible side effects

Like all medicines, Salbutamol Sulphate 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 the Salbutamol Sulphate 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; skin rash or hives, and a fall in blood pressure. You might collapse in very rare circumstances)

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

The following side effects have been reported:

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

- tremor (shakes – especially noticeable in your hands)
- headache
- feeling tense
- dizziness
- fast heartbeats

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

- muscle pain
- mouth irritation
- muscle cramps.
- palpitation

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

- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- sleep disturbances and sensing things that are not real have been reported especially in children
- abnormal heart beat
- widening of blood vessels
- throat irritation
- feeling sick
- vomiting
- a dry, sore mouth

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

- difficulty in sleeping
- difficulty in breathing or wheezing
- irregular heart-beat, especially when used with beta-blockers
- hyperactivity
- itching skin.

Not known (frequency can not be estimated from the available data)

- restriction of blood supply to the heart.

Using this inhaler may rarely lead to a build up of lactic acid or low potassium levels in your blood. Your doctor may wish you to have regular blood tests to check your blood potassium levels.

Although it is not known exactly how often this happens, some people may experience chest pain (due to heart problems such as angina). Tell your doctor as soon as possible if you develop these symptoms whilst receiving treatment with this inhaler, but do not stop taking this medicine unless told to do so.

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 (for example you need higher doses to relieve your breathing problems or your inhaler fails to give relief for at least 3 hours), 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 Salbutamol Sulphate Inhaler unless your doctor tells you to.

If you use Salbutamol Sulphate Inhaler 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.

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: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Salbutamol Sulphate Inhaler

Keep this medicine out of sight and reach of children.

Do not use Salbutamol Sulphate Inhaler after the “EXP” date which is stated on the canister and carton. The “EXP” date refers to the last day of that month.

Do not store above 30°C.

The canister contains a pressurised liquid. Do not expose the canister to temperatures higher than 50°C. Do not pierce the canister.

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 Salbutamol Sulphate Inhaler contains:

The active ingredient is salbutamol.

Each metered dose (ex-valve) contains 100 micrograms salbutamol (as sulphate).

The other ingredients are oleic acid, ethanol and HFC-134a (norflurane; a CFC-free propellant).

This medicine contains fluorinated greenhouse gases.

Each inhaler contains 17.8 g of HFC-134a (Norflurane) corresponding to 0.025 tonne CO₂ equivalent (global warming potential GWP = 1430).

What Salbutamol Sulphate Inhaler looks like and contents of the pack:

The inhaler comprises an aluminium canister fitted with a metering valve, which is inserted into a light blue standard plastic actuator fitted with a removable blue plastic mouthpiece cover, embossed with "Cipla" logo and "SALBUTAMOL CFC-free 100 mcg".

This inhaler contains 200 puffs.

Marketing Authorisation Holder

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Manufacturer

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