

Package leaflet: Information for the user
Salbutamol 2 mg/5 ml Oral Solution

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Salbutamol is and what it is used for
2. What you need to know before you take Salbutamol
3. How to take Salbutamol
4. Possible side effects
5. How to store Salbutamol
6. Contents of the pack and other information

1. What Salbutamol is and what it is used for

The active ingredient of this medicine is salbutamol which belongs to a group of medicines known as bronchodilators. Salbutamol is used to rapidly treat asthma, bronchospasm and reversible airways obstruction by widening the airways of the lungs. It is suitable for children or adults who prefer liquid medicines or are unable to use an inhaler device.

2. What you need to know before you take Salbutamol

Do NOT take Salbutamol if you:

- have an allergy (hypersensitivity) to Salbutamol Sulphate or any of the other ingredients of this medicine (see Section 6 and end of section 2).
- are in premature labour or threatened miscarriage.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Salbutamol if you:

- are diabetic, as this product may cause an increase in blood sugar levels. This effect may be further increased if you are also taking corticosteroids.
- have an irregular heartbeat / heart rhythm, including a very fast pulse.
- have an overactive thyroid.
- have acute severe asthma; your potassium levels should be monitored.
- have unstable asthma; you may need additional treatment and regular monitoring.
- need to use your asthma medication(s) more frequently to control your symptoms.
- have an enlarged prostate, as Salbutamol may cause difficulty in passing water.

Other medicines and Salbutamol

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, but especially the following:

- medicines for the treatment of high blood pressure: propranolol, guanethidine, reserpine and methyldopa
- tricyclic antidepressants
- other medicines for your asthma

If you are going to have an **operation** requiring general anaesthetic (for example chloroform, cyclopropane or halothane) please tell the medical staff you are taking Salbutamol.

Pregnancy and breast-feeding

Salbutamol should only be used in pregnancy and when breast-feeding if considered to be essential by the doctor.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

Driving and using machines

Salbutamol has no known effect on your ability to drive or use machines.

Important information about some of the ingredients of Salbutamol

Your medicine contains:-

Ethanol: This medicine contains 3.8 mg of alcohol (ethanol) in each 5 ml which is equivalent to 0.76 mg/ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Propylene glycol: This medicine contains 2.85 mg propylene glycol per 5 ml dose which is equivalent to 0.57 mg/ml.

Sodium benzoate: This medicine contains 7.5 mg sodium benzoate in each 5 ml which is equivalent to 1.5 mg/ml.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

3. How to take Salbutamol

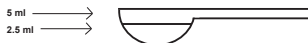
Always take the product exactly as advised. You should check with your doctor or pharmacist if you are not sure.

Only to be taken by mouth. Shake the bottle well before measuring the dose in the 5 ml plastic spoon provided.

For doses less than 5 ml

When measuring a (1 mg) half 5 ml dose, the spoon should be filled up to the 2.5 ml mark indicated on the spoon. Please see diagram below.

An oral syringe may be used to measure doses less than 5 ml.



The usual dose is:

Adults:	Two 5 ml spoonfuls (10 ml), 3 or 4 times per day, which may be increased to a maximum of four 5 ml spoonfuls (20 ml), 3 or 4 times per day. Minimum starting dose is one 5 ml spoonful (5 ml), 3 or 4 times per day.
Children aged 2 – 6 years:	Half to one 5 ml spoonful (2.5 - 5 ml), 3 or 4 times per day.
Children aged 6 – 12 years:	One 5 ml spoonful (5 ml), 3 or 4 times per day.
Children over 12 years:	One to two 5 ml spoonfuls (5 - 10 ml), 3 or 4 times per day.
Elderly patients and patients unusually sensitive to this class of medicine:	Start treatment with one 5 ml spoonful (5 ml), 3 or 4 times per day.

If the medicine does not seem to be working as well as usual, TELL YOUR DOCTOR AS SOON AS POSSIBLE. It may be that your chest condition is getting worse and you need a different medicine. DO NOT TAKE EXTRA ORAL SOLUTION unless told to by your doctor.

Salbutamol 2 mg/5 ml oral solution 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.

If you use Salbutamol 2 mg/5 ml oral solution more than twice a week to treat your asthma symptoms, not including preventative 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.

If you take more Salbutamol than you should:

If you or someone else takes too much Salbutamol, you should contact your doctor or pharmacist who will recommend what action you should take.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky
- hyperactivity
- acid build 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 Salbutamol

If you miss a dose, take it as soon as you remember and take any remaining doses for that day at evenly spaced times.

Do not take a double dose to make up for the forgotten dose.

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

4. Possible side effects

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

Allergic reactions (affects less than 1 in 10,000 people)

You should STOP using Salbutamol and seek advice from your doctor if you experience a rare allergic reaction, including skin rashes, difficulty breathing, dizziness or collapse.

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:

Very common (may affect more than 1 in 10 people)

- feeling shaky

Common (may affect up to 1 in 10 people)

- headache
- muscle cramps

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

- changes in the salt balance of your body
- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilation)

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

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability
- muscle tension

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

- chest pain, due to heart problems such as angina. Tell your doctor, pharmacist or nurse 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 or pharmacist. 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 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

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Do not use Salbutamol after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month. Keep container in the outer carton.

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. Contents of the pack and other information

What Salbutamol contains:

- The **active substance** is Salbutamol Sulphate equivalent to 2 mg Salbutamol per 5 ml.
- The **other ingredients** are xanthan gum (E415), glycerol (E422), sodium citrate, acesulfame potassium (E950), sodium benzoate (E211), citric acid monohydrate, raspberry cola flavour (which contains: ethanol, propylene glycol (E1520), polysorbate (E423), nutmeg oil, safrole and cinnamic aldehydes) and purified water. (See end of section 2 for information on ethanol, sodium benzoate and sodium).

What Salbutamol looks like and contents of the pack

Salbutamol is a raspberry cola flavoured sugar-free oral solution, available in 100 ml and 150 ml HDPE bottles, or in 100 ml, 150 ml and 200 ml amber glass bottles.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbray, Clonmel, Co. Tipperary, Ireland.

PL 04917/0033

This leaflet was last revised in 12/2023