

PHARMANIAGA SALBUTAMOL RESPIRATOR SOLUTION

Salbutamol sulphate (0.5% w/v)

What is in this leaflet-

1. What Salbutamol Respirator Solution is used for
2. How Salbutamol Respirator works
3. Before you use Salbutamol Respirator Solution
4. How to use Salbutamol Respirator Solution
5. While you are using it
6. Side effects
7. Storage and Disposal of Salbutamol Respirator Solution
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What Salbutamol Respirator Solution is used for

Salbutamol Respirator Solution is used to relieve bronchospasm (constriction of the airways).

How Salbutamol Respirator Solution works

Salbutamol helps to open up the airways in the lungs. It works mainly on the muscles in the lungs to make breathing easier.

Before you use Salbutamol Respirator Solution

- When you must not use it

Do not take this medicine if:

- you are allergic to salbutamol sulphate or any other ingredients of this medicine (listed in Product Description)
- you have threatened abortion during the first or second trimesters.

- Before you start to use it

Check with your doctor or pharmacist before taking Salbutamol Respirator Solution if:

- you are diabetic.
- you have thyrotoxicosis (excessive thyroid hormone).

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using

any medicine. Use of salbutamol during breastfeeding is not recommended unless necessary, since it may pass into breast milk and its effects on the baby are unknown.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- Heart medication eg: Propranolol
- Antidepressant medication
- Other asthma medication
- Steroids
- Water pill

How to use Salbutamol Respirator Solution

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Salbutamol Respirator Solution is to be used with a respirator or nebuliser, only under the direction of a physician. The solution must not be injected.

Intermittent treatment

Intermittent treatment may be repeated four times daily.

- **Adults** - The usual dose is 0.5ml to 1 ml (2.5 – 5.0mg) of Salbutamol Respirator Solution diluted to a final volume of 2.0 or 2.5ml using sterile normal saline as a diluent. This solution is inhaled from a nebuliser, usually for about 10 minutes.

Some adult patients may require up to 2.0ml (10mg), in which case the undiluted solution may be used for nebulisation. It usually takes 3-5 minutes.

- **Children under age of 12 years-** The usual dose is 0.5ml (2.5 mg) of Salbutamol Respirator Solution diluted to 2.0 or 2.5ml using sterile normal saline solution as diluent. Some children may require up to 1ml (5 mg).

Your doctor may have told you to dilute the Salbutamol Respirator Solution with a sterile normal saline solution before using it in the nebuliser. Remember to follow the instructions for dilution.

Continuous treatment.

- The usual dose is 1 to 2 mg of salbutamol per hour.
- This dose can be obtained by diluting 1ml – 2ml (5mg – 10mg) of Salbutamol Respirator Solution to 100ml with sterile normal saline solution to produce a solution containing 50 or 100 micrograms/ml of salbutamol, and inhaling the mist from a suitable nebuliser.

- When to use it

Use as directed by your doctor or pharmacist. Salbutamol has a duration of action of 4 to 6 hours in most patients.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause:

- Seizures
- Angina (chest pain)
- Hypertension or hypotension
- Tachycardia (heart beating faster than normal)
- Arrhythmias (irregular heart rhythm)
- Nervousness
- Headache
- Tremor (shaking)
- Dry mouth
- Palpitation (irregular, fast, or strong heartbeats)
- Nausea
- Dizziness
- Fatigue (tiredness)
- Insomnia (sleeping difficulty)
- Hypokalemia (low potassium in blood)

While you are using Salbutamol Respirator Solution

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Salbutamol Respirator Solution.

Tell your doctor immediately if you become pregnant while using this medication.

Take Salbutamol Respirator Solution only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Salbutamol Respirator Solution to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how Salbutamol Respirator Solution affects you.

Not to let the solution or mist enter the eye.

Doctors should regularly assess asthma control with lung tests, especially in severe or unstable cases. Salbutamol may lower potassium levels or raise blood sugar, particularly in those with diabetes or on steroids, so blood monitoring may be needed. Additional treatment, like corticosteroids, may be required for better control

Side effects

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

Possible side effects are:

- Tremor (shaking)
- Headaches
- Tachycardia (heart beating faster than normal)
- Hypersensitivity (swelling, itchy skin rash, breathing difficulty, low blood pressure, and collapse)
- Muscle cramps
- Hypokalaemia (low blood potassium in blood)
- Mouth and throat irritation
- Increase heart rate
- Peripheral vasodilatation (Widening of the small blood vessels near the surface of the body)
- Acute angle closure (a sudden blockage in the eye's drainage system, leading to a rapid increase in pressure)

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Salbutamol Respirator

- Storage

Store below 30°C. Protect from light. Keep container tightly closed.

After dilution with normal saline, store at room temperature or in refrigerator (2°C-8°C).

- Disposal

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.

Product Description

- What it looks like

Colourless to pale yellow solution

- Ingredients

- Active ingredient
 - salbutamol sulphate
- Inactive ingredients
 - Benzalkonium chloride solution
 - Sulphuric acid
 - Purified water

- MAL number(s):

MAL19985179AZ

Manufacturer and Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia

Date of revision

04/06/2025

Serial Number

NPRA(R4/1)070525/00033