

**Package Leaflet: Information for the User**

Ventolin Respirator Solution

5 mg/ml**Salbutamol (as sulphate)****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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Ventolin Respirator Solution is and what it is used for
- 2 What you need to know before you take Ventolin Respirator Solution
- 3 How to take Ventolin Respirator Solution
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1 What Ventolin Respirator Solution is and what it is used for

Ventolin Respirator Solution contains a medicine called salbutamol. This 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.

Ventolin Respirator Solution is used to treat breathing problems in people with asthma and other chest illnesses. It is usually given to people who suffer quite badly from these conditions when other forms of treatment do not help enough. Ventolin Respirator Solution is also used to treat severe attacks of asthma.

Ventolin Respirator Solution must only be used by inhalation from a nebuliser and must not be injected or swallowed.

2 What you need to know before you take Ventolin Respirator Solution**Do not take Ventolin Respirator Solution if:**

- you are allergic to salbutamol sulphate or any of the other ingredients of this medicine (listed in Section 6).
- you unexpectedly go into early labour (premature labour) or threatened abortion.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Ventolin Respirator Solution if:

- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your doctor may start or increase a medicine to control your asthma such as an inhaled corticosteroid.
- you have high blood pressure
- you are diabetic
- you have an overactive thyroid gland
- you have a history of heart problems such as an irregular or fast heartbeat or angina.
- you use another nebuliser solution e.g. ipratropium bromide, make sure the mist does not get in your eyes. This can be prevented by using a mouthpiece instead of a face mask or goggles.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.
- you have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma.

Other medicines and Ventolin Respirator Solution

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This includes herbal medicines. Remember to take this medicine with you if you go to hospital. In particular tell your doctor, nurse or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat
- other medicines for your asthma.

Pregnancy, breast-feeding and fertility

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

Ventolin is not likely to affect you being able to drive or use any tools or machines.

Ventolin Respirator Solution contains 0.1 mg/ml benzalkonium chloride in each dosage unit.

Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

3 How to take Ventolin Respirator Solution

- Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
- Ventolin Respirator Solution **must only be used by inhalation** from a nebuliser, and must not be injected or swallowed. The nebuliser produces a fine mist which you breathe in through a face mask or a mouthpiece. Make sure that you know how to use it properly. If you have problems ask your doctor, nurse or pharmacist.
- Do not let the Ventolin Respirator Solution, or the mist produced by the nebuliser, get into your eyes.
- Use your nebuliser in a well ventilated room as some of the mist will be released into the air and may be breathed in by others.
- Make sure you know how, when and how much solution you should use.

Your doctor may have prescribed either intermittent (occasional short bursts) or continuous treatment with Ventolin Respirator Solution.

Children under 18 years should only use a nebuliser to take reliever medications under the care of a doctor with expertise in the management of asthma so that deterioration in asthma control can be detected and treated without delay.

Only use the nebuliser recommended by your doctor and supervise your child while they are using the nebuliser.

Seek urgent medical assistance if the nebulised medication is not working, even if there is short-term recovery following use of prescribed nebulised medication.

Intermittent treatment

- **Adults and adolescents aged 12 years and over** - The usual dose is 0.5 ml to 1 ml of Ventolin Respirator Solution (2.5 to 5 mg salbutamol). Some patients may require up to 2 ml (10 mg salbutamol).
- **Children aged 18 months to 12 years** - The usual dose is 0.5 ml to 1 ml (2.5 to 5 mg salbutamol) of Ventolin Respirator Solution, given four times daily.

Your doctor may have told you to dilute the Ventolin 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 1 or 2 ml of Ventolin Respirator Solution to 100 ml 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.

How to use your Ventolin Respirator Solution

- 1 Prepare the nebuliser for filling.
- 2 Measure out the right quantity of Ventolin Respirator Solution and put it in the nebuliser bowl.
- 3 Add the right amount of sterile normal saline solution (make sure your doctor has told you how much to use).
- 4 Put the top on the nebuliser bowl and shake it gently to mix the contents.
- 5 Assemble the nebuliser and use it as directed.
- 6 After use throw away any solution remaining in the nebuliser bowl. Clean your nebuliser in the recommended way.

If you take more Ventolin Respirator Solution than you should

If you take more than you should, talk to a doctor as soon as possible.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky
- hyperactivity

These effects usually wear off in a few hours.

If you forget to take Ventolin Respirator Solution

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Ventolin Respirator Solution

Do not stop taking Ventolin Respirator Solution without talking to your doctor.

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

4 Possible side effects

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic Reactions (may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking Ventolin and see a doctor straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and 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 may affect up to 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:

Common (may affect up to 1 in 10 people)

- feeling shaky
- headache.

Uncommon (may affect up to 1 in 100 people)

- mouth and throat irritation
- muscle cramps.

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

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation).

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

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

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, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.
- a condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath, cold feet and hands, irregular heartbeat or thirst.

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, 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 Ventolin unless your doctor tells you to.

5 How to store Ventolin Respirator Solution

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C. Keep the bottle in the outer carton in order to protect from light.
- Do not leave solution in your nebuliser once you have finished a treatment.
- After opening the bottle:
 - note the day of opening.
 - add 4 weeks to this date. This will be the 'discard after' date.
 - do not use any unused Ventolin Respirator Solution after the 'discard after' date but return it to your pharmacist for destruction.
- If the bottle has not been opened, do not use the solution after the expiry date which is stated on the bottle label and carton after 'EXP'. The date refers to the last day of that month.
- If you are told to stop taking this medicine return any unused Ventolin Respirator Solution to your pharmacist to be destroyed.

Do not throw away 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 Ventolin Respirator Solution contains**

- The active substance is salbutamol (as sulphate).
- The other ingredients are water, benzalkonium chloride and sulfuric acid.
- Each 20 ml bottle contains 100 mg of salbutamol (as sulphate).

What Ventolin Respirator Solution looks like and contents of the pack

Ventolin Respirator Solution comes in an amber coloured glass bottle containing 20 ml. The solution is colourless to light yellow in colour.

Marketing Authorisation Holder:

Glaxo Wellcome UK Limited
980 Great West Road, Brentford, Middlesex, United Kingdom

Manufacturer:

Glaxo Operations UK Limited*, Barnard Castle, United Kingdom
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To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via: gulf.safety@gsk.com

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This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

