



**Patient information leaflet**  
**(For All Products not subject to Medical Prescription)**

SALBUCORT(Salbutamol Pressurised Inhalation BP, 100 mcg, 200 Metered Doses)

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Read all of this leaflet carefully before you start taking this medicine.**

Keep this leaflet. You may need to read it again.

If you have any further questions, please 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 you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

**In this leaflet:**

1. What Salbutamol Inhaler is and what it is used for
2. Before you take Salbutamol Inhaler
3. How to take Salbutamol Inhaler
4. Possible side effects
5. How to store Salbutamol Inhaler
6. Further information

**1. WHAT SALBUTAMOL INHALER IS AND WHAT IT IS USED FOR**

Salbutamol Inhaler 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.

**Module 1- Administrative and Prescribing Information**

Salbutamol Inhaler is used to treat breathing problems in people with asthma and similar conditions. This includes relieving and preventing asthma brought on by 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 Inhaler contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Salbutamol Inhaler. This will make no difference to how your medicine works.

**2. BEFORE YOU TAKE SALBUTAMOL INHALER****Do not use Salbutamol Inhaler if:**

- you are allergic to salbutamol sulfate 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 Salbutamol Inhaler 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 have an overactive thyroid gland
- you have a history of heart problems such as an irregular or fast heartbeat or angina.
- 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.

**Other medicines and Salbutamol Inhaler**

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.

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

**Module 1- Administrative and Prescribing Information**

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

**3. HOW TO TAKE SALBUTAMOL INHALER**

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

**Adults and adolescents aged 12 years and over**

- to relieve asthma - One or two puffs.
- to prevent asthma - Two puffs 10-15 minutes before exercise or exposure to a “trigger”.
- for regular treatment - Two puffs up to 4 times a day.
- the maximum dose is 8 puffs in a 24 hour period.

**Children under 12 years of age**

- to relieve asthma - One puff. Two puffs if required.
- to prevent asthma - One puff 10-15 minutes before exercise or exposure to a “trigger”.

Two puffs if required.

- for regular treatment - Two puffs up to 4 times a day.
- the maximum dose is 8 puffs in a 24 hour period.

**Instructions for use**

- To help identify that the inhaler is Ventolin, there is an embossed letter V on the plastic case.
- Salbutamol Inhaler produces a fine mist, which you inhale through your mouth into your lungs. Your doctor, nurse or pharmacist should show you how to use your inhaler. If you are not sure ask your doctor, nurse or pharmacist.
- Each Evohaler canister provides 200 puffs.

Do not use your inhaler more often than the doctor told you to. Tell your doctor if your medicine does not seem to be working as well as usual, as your chest problem may be getting worse and you may need a different medicine.

**Module 1- Administrative and Prescribing Information**

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

**Cleaning your inhaler**

To stop your inhaler blocking, it is important to clean it at least once a week.

**To clean your inhaler:**

- Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
- Rinse the plastic casing thoroughly under warm running water.
- Dry the plastic casing thoroughly inside and out.
- Replace the metal canister into the plastic casing and put on mouthpiece cover.

Do not put the metal canister in water.

**If you take more Salbutamol Inhaler 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 Salbutamol Inhaler**

- 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 Salbutamol Inhaler**

Do not stop taking Salbutamol Inhaler 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**

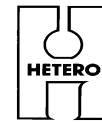
**If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.**

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 Salbutamol Inhaler and see a doctor straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat

**Module 1- Administrative and Prescribing Information**

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:

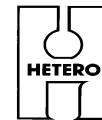
- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse.

**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

**Module 1- Administrative and Prescribing Information**

medicine. Do not take extra doses of Salbutamol Inhaler unless your doctor tells you to.

**5. HOW TO STORE SALBUTAMOL INHALER**

- Keep this medicine out of the sight and reach of children.
- Store below 30°C. Protect from frost and direct sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not puncture, break or burn it even when apparently empty.
- Do not use this medicine after the expiry date, which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

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 to protect the environment.

**6. FURTHER INFORMATION****What Salbutamol Inhaler contains**

- The active substance is salbutamol sulfate.
- The other ingredient is HFA 134a.

**What Salbutamol Inhaler looks like and contents of the pack**

Salbutamol Inhaler comprises an aluminium alloy can sealed with a metering valve, actuator and dust cap.

Each canister contains 200 doses of 100 micrograms of salbutamol (as salbutamol sulfate).

**Marketing Authorisation Holder and Manufacturer****Marketing Authorisation Holder:**

**Name:** Hetero Labs Limited  
**Business Address:** 7-2-A2, Hetero Corporate,  
Industrial Estates, Sanath Nagar,  
Hyderabad-500018, Telangana.  
**Country:** INDIA

**Manufacturer:**



**Module 1- Administrative and Prescribing Information**

(Company) Name : M/s. Hetero Labs Limited Unit-VII  
Address : Sy.No.50, Plot No.14, Phase-III, IDA,  
Jeedimetla, Hyderabad-500 0:55,  
Telangana State, India.  
Country : India  
Telephone : +91 40-23091563/64