VENTOLIN SYRUP

Salbutamol sulphate (2 mg/5 ml)

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What VENTOLIN is used for VENTOLIN is used for the relief of:

- · bronchial asthma
- chronic bronchitis (inflammation of the airways that carry air to your lungs).
- emphysema (damages to the air sacs (alveoli) in your lungs)

The syrup is used when children and adults cannot use an inhaler device

How VENTOLIN works

VENTOLIN Syrup contains a medicine called salbutamol. This belongs to a group of medicines called 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.

Before you use VENTOLIN

- When you must not use it

Do not take VENTOLIN Syrup:

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

- Before you start to use it

Talk to your doctor, nurse or pharmacist before taking VENTOLIN Syrup if:

- you have hypoxia (deficiency in the amount of oxygen reaching the tissues)
- · vou are diabetic
- you have an overactive thyroid gland
- you have severe heart disease (such as ischaemic heart disease, irregular heart rhythm, severe heart failure).

Tell your doctor if you experience symptoms such as chest pain, dyspnoea (shortness of breath) or other symptoms of worsening heart disease.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

- Taking other medicines

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 have to go to hospital.

In particular tell your doctor, nurse or pharmacist if you are taking: medicines for an irregular or fast heartbeat such as betablockers (propranolol) or other medicines for your asthma, such as steroids or xanthines derivatives.

How to use VENTOLIN

- How much to use

Children between 2 and 6 years: the usual dose is 2.5ml to 5ml, three or four times a day.

Children between 6 and 12 years: the usual dose is 5ml, three or four times a day.

Children over 12 years: the usual dose is 5ml to 10ml, three or four times a day.

Adults: the usual dose is 5ml to 20ml, three or four times a day.

Elderly: the usual dose is 5ml, up to three times a day.

- When to use it

Always take this medicine exactly as your doctor has told you

- How long to use it

Check with your doctor, nurse or pharmacist if you are not sure.

- If you forget to use it

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 double dose to make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken 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 VENTOLIN Syrup may cause:

- Tachycardia (an abnormally rapid heart rate)
- Tremor
- · Hyperactivity
- · Low blood potassium level
- Lactic acidosis (buildup of lactic acid in the body)
- · Nausea and vomiting
- · High blood glucose

These effects usually wear off in a few hours.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking VENTOLIN Syrup

Tell your doctor immediately if you are pregnant during the course of this medication.

- Things you must not do

Do not stop taking VENTOLIN Syrup without talking to your doctor.

Do not take any new medicines without consulting your doctor.

Do not give VENTOLIN Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

VENTOLIN Syrup contains sodium. This should be taken into consideration if you are on a controlled sodium diet.

VENTOLIN Syrup is sugar free.

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 syrup unless your doctor tells you to.

Side Effects

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

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
- Tachycardia (an abnormally rapid heart rate)
- Palpitations (irregular heartbeat)

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)
- Cardiac arrhythmias (irregular heartbeat) including atrial fibrillation (an irregular and often very fast heart rate), supraventricular tachycardia (a rapid heart rate) and extrasystoles (a heartbeat outside the normal rhythm, as often occurs in normal individuals).

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

- hyperactivity
- Muscle tension
- Allergic reactions. If you have an allergic reaction, stop taking VENTOLIN Syrup and see a doctor immediately. 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.

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

 Myocardial ischaemia (a condition of insufficient blood flow to the heart muscle via the coronary arteries, often result in chest pain).

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.

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

Storage and Disposal of VENTOLIN

- Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C. Protect from light If your pharmacist has diluted syrup (with purified water):

- Do not use after 28 days.
- Follow the instructions on the pharmacist's label.
- Wipe the neck bottle after use.
- Do not use Ventolin syrup after the expiry date, which is stated on the bottle label and carton after 'EXP'. The expiry date refers to the last day of that month.

- 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

Ventolin syrup is a clear orange viscous liquid free from visible foreign matter, with the odour and flavor of oranges and a sweet taste.

Ventolin syrup is available in 100ml amber plastic bottle.

- Ingredients

- Active ingredient

Each 5ml contains 2 mg salbutamol (as salbutamol sulphate BP)

- Inactive ingredient(s)

Sodium citrate dihydrate, Citric acid monohydrate, Hydroxypropyl methylcellulose, Sodium benzoate, Saccharin sodium, Sodium chloride, Orange flavour, Purified water

- MAL number

MAL07010969ACRZ

Manufacturer

PT. Sterling Products Indonesia Jl. Pulobuaran Raya Kav. III DD/2,3,4 Kawasan Industri Pulogadung Jakarta Timur, Indonesia

Product Registration Holder

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