GSK logo

Package Leaflet: Information for the User

Ventolin Syrup

salbutamol sulfate

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 Syrup is and what it is used for
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What Ventolin Syrup is and what it is used for

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.

Ventolin Syrup is used to treat breathing problems in people with asthma and similar conditions. The syrup is used when children and adults cannot use an inhaler device.

2 What you need to know before you take Ventolin Syrup

Do not take Ventolin Syrup:

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

Warnings and precautions

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

- 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 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 Ventolin Syrup

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
- other medicines for your asthma.

Taking Ventolin Syrup with food and drink

You can take Ventolin Syrup at any time of day, with or without food.

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 or pharmacist for advice before taking this medicine.

Driving and using machines

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

Important information about some of the ingredients of Ventolin Syrup

Ventolin Syrup contains 5.6 mg sodium (main component of cooking/table salt) in each 5 ml dose. This is the equivalent to 0.28% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 10 mg sodium benzoate per 5 ml dose.

This medicine contains 1.9 mg of propylene glycol in each 5 ml dose.

This medicine contains 0.00003325 mg (very small amounts) benzyl alcohol in each dosage unit. Benzyl alcohol may cause allergic reactions. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3 How to take Ventolin Syrup

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

Taking this medicine

- use a 5 ml plastic spoon or oral syringe to take the syrup, they are available from your pharmacist
- shake well before use
- 2.5 ml of undiluted syrup provides a dose of 1 mg and 5 ml provides a dose of 2 mg.

Children between 2 and 6 years

the usual dose is 2.5 ml to 5 ml, three or four times a day.

Children between 6 and 12 years

• the usual dose is 5 ml, three or four times a day.

Children over 12 years

the usual dose is 5 ml to 10 ml, three or four times a day.

Adults (over 18 years)

• the usual dose is 5 ml to 20 ml, up to four times a day.

Elderly (over 65 years)

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

If you take more Ventolin Syrup 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
- 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 Ventolin Syrup

- 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 Syrup

Do not stop taking Ventolin Syrup 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

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 (affects less than 1 in 10,000 people)

If you have an allergic reaction, stop taking Ventolin Syrup 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 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)

• Your heart beats too fast, too slow or irregularly (cardiac arrythmia)

- 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
- 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, 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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.

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 Syrup unless your doctor tells you to.

5 How to store Ventolin Syrup

- Keep this medicine out of the sight and reach of children.
- Store undiluted syrup below 30°C.
- Protect from light.
- If your pharmacist has diluted your syrup (with purified water):
 - store it below 25°C
 - do not use after 28 days
 - follow the instructions on the pharmacist's label.
- Wipe the neck of the 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.
- If you are told to stop taking this medicine return any unused Ventolin Syrup to your pharmacist to be destroyed.

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 Contents of the pack and other information

What Ventolin Syrup contains

- The active substance is salbutamol sulfate.
- The other ingredients are water, sodium citrate, citric acid monohydrate, hydroxypropylmethylcellulose, saccharin sodium, salt (sodium chloride), the preservative sodium benzoate (E211), benzyl alcohol, propylene glycol (present as a constituent of orange flavour) and orange flavour.

What Ventolin Syrup looks like and contents of the pack

Ventolin Syrup comes in an amber coloured glass bottle. It is sealed with a child resistant plastic cap.

Each bottle contains 150 ml of syrup.

Each bottle contains 2 mg of salbutamol in each 5 ml of undiluted syrup.

Marketing Authorisation Holder

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Manufacturer

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Ventolin Syrup
Reference number 10949/0088

This is a service provided by the Royal National Institute of Blind People.

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