GSK logo

Package Leaflet: Information for the User

Ventolin 2 mg/5 ml Oral Solution

salbutamol (as 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet

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1 What Ventolin Oral Solution is and what it is used for

Ventolin 2 mg/5 ml Oral Solution (called 'Ventolin Oral Solution' in this leaflet) 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 Oral Solution is used to treat breathing problems in adults, adolescents and children with asthma, bronchitis and emphysema.

2 What you need to know before you take Ventolin Oral Solution

Do not take Ventolin Oral Solution:
- if you are allergic (hypersensitive) to salbutamol sulfate or any of the other ingredients of Ventolin Oral Solution (listed in Section 6).

Warnings and precautions
Talk to your doctor, nurse or pharmacist before taking Ventolin Oral Solution 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 suffer from acute severe asthma (your doctor may need to carry out blood tests to monitor the amount of potassium in your blood)

If your asthma or breathing gets worse tell your doctor straight away. Your chest condition may be getting worse and you could become seriously ill.

Other medicines and Ventolin Oral Solution
Please tell your doctor, nurse or pharmacist if you are taking or have recently taken 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 propranolol
- other medicines for your asthma
- medicines used to treat high blood pressure such as guanethidine and methyldopa
- reserpine (used to treat high blood pressure or severe agitation)
- tricyclic antidepressants
- xanthine derivatives (such as theophylline) or steroids to treat asthma
- water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition
- anaesthetics such as chloroform, cyclopropane and halothane

Ventolin Oral Solution with food and drink
You can take Ventolin Oral Solution 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 Oral Solution 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 Oral Solution
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.

This medicine contains 10 mg sodium benzoate per 5ml which is the equivalent to 2 mg/ml. Sodium benzoate may increase jaundice (yellowing of skin and eyes) in newborn babies (up to 4 weeks old).

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

This medicine contains trace amounts of benzyl alcohol in each dosage unit. Benzyl alcohol has been linked to the risk of severe side effects including breathing problems (called 'gasping syndrome') in young children. 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 Oral Solution

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

Taking this medicine

- use a 5 ml plastic spoon or oral syringe to take the Oral Solution, they are available from your pharmacist

- shake well before use
- 2.5 ml of undiluted Oral Solution provides a dose of 1 mg and 5 ml provides a dose of 2 mg

Adults (over 18 years)
The recommended dose is 10 ml to 20 ml, three or four times a day.

Use in children and adolescents
- Children between 2 and 6 years: The recommended dose is 2.5 ml to 5 ml, three or four times a day
- Children between 6 and 12 years: The recommended dose is 5 ml, three or four times a day
- Children and adolescents over 12 years: The recommended dose is 5 ml to 10 ml, three or four times a day

Elderly (over 65 years)
The recommended dose is 5 ml, three or four times a day.

If you take more Ventolin Oral 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
- acid builds 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 Oral 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 Oral Solution
Do not stop taking Ventolin Oral 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

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 Oral Solution 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)
- a low level of potassium in your blood,
- your heart beats too fast, too slow or irregularly (cardiac arrhythmia),
- increased blood flow to your extremities (peripheral vasodilatation).

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

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 Oral Solution unless your doctor tells you to.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Ventolin Oral Solution

- Keep this medicine out of the sight and reach of children
- Do not store above 25°C
- Store in the outer carton in order to protect from light
- If your pharmacist has diluted your Oral Solution (with purified water):
  - store it below 25°C
  - do not use after 4 weeks
  - follow the instructions on the pharmacist's label
- Do not use Ventolin Oral Solution 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 Oral Solution 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 Oral Solution contains

- The active substance is salbutamol (as sulfate)
- The other ingredients are purified water, sodium citrate, citric acid monohydrate, hypromellose, saccharin sodium, sodium chloride, the preservative sodium benzoate (E211) and orange flavour (contains benzyl alcohol & propylene glycol).

What Ventolin Oral Solution looks like and contents of the pack

Ventolin Oral Solution comes in an amber coloured glass bottle. It is sealed with a child resistant plastic cap.
Each bottle contains 150 ml of Oral Solution.
Each bottle contains 2 mg of salbutamol in each 5 ml of undiluted Oral Solution.

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