

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed according to a physician's prescription only

Ventolin Syrup

Each teaspoon (5 ml) contains:

Salbutamol (as Sulfate) 2 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – “Important information about some of the ingredients in the medicine” and section 6 – “Additional information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ventolin Syrup is intended for the relief of bronchospasm related to asthma, chronic bronchitis and emphysema.

Therapeutic group:

Selective beta-2 adrenoceptor agonist.

Ventolin Syrup contains a medicine called salbutamol. It 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 when children and adults cannot use an inhaler device.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to salbutamol sulfate or to any of the additional ingredients contained in this medicine (as listed in section 6).
- Non-I.V. formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion.

Special warnings regarding use of the medicine

Before the treatment with Ventolin Syrup, tell the physician 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 diuretics, sometimes used to treat high blood pressure or a heart condition.

Children and adolescents

Ventolin Syrup is not intended for children and babies below the age of 2 years.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially if you are taking:

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

Using the medicine and food

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before taking this medicine.

Driving and using machines

It is unlikely that this medicine will affect you being able to drive or use any tools or machines.

Important information about some of the ingredients in the medicine

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. Ventolin Syrup is sugar-free.

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 (a very small amount) 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 physician.

Ask your physician 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 SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

Taking this medicine

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

Do not exceed the recommended dose.

Opening instructions - to remove the cap, press down, while simultaneously turning left (counterclockwise).

Closing instructions - close the bottle tightly with the cap, turning it to the right (clockwise) until it is completely closed.

If you accidentally have taken a higher dosage

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

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 forgot to take the medicine

- If you forgot 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 the medicine

Do not stop taking Ventolin Syrup without talking to your physician.

Adhere to the treatment regimen recommended by your physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ventolin Syrup may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

The following side effects may happen with this medicine:

Allergic reactions (affect less than 1 in 10,000 people)

If you have an allergic reaction, stop taking Ventolin Syrup and refer to a physician 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 physician 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 physician as soon as possible. **Do not stop using this medicine unless told to do so.**

Additional side effects

Tell your physician if you have any of the following side effects, which may also happen when taking this medicine:

Very common side effects

These may affect **more than 1 in 10** people:

- feeling shaky.

Common side effects

These may affect **up to 1 in 10** people:

- headache
- muscle cramps.

Rare side effects

These may affect **up to 1 in 1,000** people:

- Your heart beats too fast, too slow or irregularly (cardiac arrhythmia)
- a low level of potassium in the blood
- increased blood flow to the extremities (peripheral dilatation).

Very rare side effects

These 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 is not known:

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

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, refer to your physician as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra doses of Ventolin Syrup unless your physician tells you to.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Undiluted syrup - Do not store above 30°C. Protect from light.
- Use within 28 days from opening and no later than the expiry date of the product.
- If your pharmacist has diluted your syrup (with purified water):
 - store the diluted syrup below 25°C and protect from light.
 - do not use after 28 days.
 - follow the instructions on the pharmacist's label.
- Wipe the neck of the bottle after use.
- If you are told to stop taking this medicine return the Ventolin Syrup to your pharmacist to be destroyed.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient the medicine also contains:
Citric acid monohydrate, hydroxypropyl methylcellulose 2910, the preservative sodium benzoate, sodium citrate, sodium chloride, saccharin sodium, propylene glycol (present as a constituent of orange flavour), orange flavour IFF 17.42.8187 and purified water.
- What the medicine looks like and the contents of the package:
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.
The package contains a double-ended measuring spoon. One side of the spoon with a capacity of 5 ml and the other side with a capacity of 2.5 ml.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 050-54-24044.

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