

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

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

Ventolin Inhaler CFC Free

Each metered dose contains:

salbutamol (as sulfate) 100 mcg/dose

Ventolin Inhaler contains 200 metered doses.

For the list of the inactive and allergenic ingredients in the medicine, see 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 Inhaler is a short-acting (4-6 hour) bronchodilator with fast (within 5 minutes) onset in reversible airways obstruction.

It is particularly suitable for the relief and prevention of asthma symptoms.

It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognized by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).

Ventolin Inhaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.

Therapeutic group:

Selective β -2 adrenoceptor agonist.

Ventolin Inhaler contains a medicine called salbutamol. It 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 Inhaler contains an ingredient called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently from Ventolin Inhaler. This will make no difference to how the medicine works.

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 (listed in section 6).

Special warnings regarding use of the medicine

Before the treatment with Ventolin Inhaler, tell the physician if:

- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your physician 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 diuretics, sometimes used to treat high blood pressure or a heart condition.

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 inform the physician or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat (especially from the beta blocker class such as propranolol).
- other medicines for your asthma.

Using the medicine and food

You can use Ventolin Inhaler 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 using this medicine.

Driving and using machines

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

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.

The recommended dosage is usually:

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 allergens.
- 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. The dosage can be increased to two puffs if required.
- to prevent asthma - one puff 10-15 minutes before exercise or exposure to allergens. The dosage can be increased to 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.
- You may find an adapter (spacer), with or without a face mask, useful if you have to give Ventolin Inhaler to a baby or a child under the age of 5. Speak to your physician if you think you might need one of these.

Do not exceed the recommended dose.

Follow the **Instructions for use** provided at the end of the leaflet.

If you accidentally have taken a higher dosage

If you take more than you should, talk to a physician 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 have inhaled an overdose or if a child has accidentally inhaled some medicine, immediately contact a physician or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine

If you forget to take this medicine at the scheduled time, take it as soon as you remember it. However, if it is time for the next dose, skip the forgotten dose. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine

Even if your health condition improves, do not stop treatment with the medicine without consulting the 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 further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

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

As with any medicine, use of Ventolin Inhaler 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 (these may affect **up to 1 in 10,000** people)

If you have an allergic reaction, stop using Ventolin Inhaler and see 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 lightheaded, 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 effects may affect **up to 1 in 10** people.

If any of these effects happen to you, talk to your physician as soon as possible.

Do not stop using this medicine unless told to do so.

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

Common side effects

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

- feeling shaky
- headache.

Uncommon side effects

These may affect **up to 1 in 100** people:

- mouth and throat irritation
- muscle cramps.

Rare side effects

These 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 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.

The following side effects may also happen, but their frequency 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, talk 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 Inhaler, 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.
- 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 expose it to temperatures higher than 50°C. Do not puncture, break or burn the inhaler even if it is empty.
- 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: HFA 134a.
- What the medicine looks like and the contents of the package:
Ventolin Inhaler comprises an aluminium alloy canister sealed with a metering valve, a plastic casing and a mouthpiece cover.
Each canister contains 200 metered doses of 100 micrograms of salbutamol (as sulfate).
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Wellcome, S.A., Burgos, Spain.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 113-25-29560.

Instructions for use:

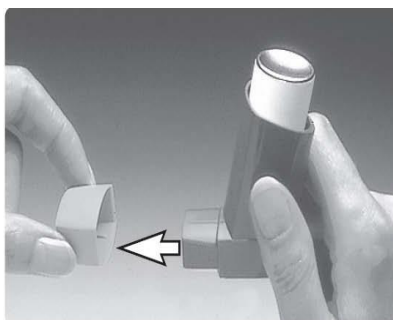
- Ventolin Inhaler produces a fine mist, which you inhale through your mouth into your lungs. Your physician, nurse or pharmacist should show you how to use your inhaler. If you are not sure, ask your physician, nurse or pharmacist.
- Each inhaler canister provides 200 inhalation doses (puffs).

Do not use your inhaler more often than the physician told you to. Tell your physician 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.

Your physician may have told you to take a dosage higher than usual as an emergency treatment if your breathing or wheezing gets very bad. It is very important that you adhere to your physician's instructions as to how many puffs to take and how often to use your inhaler.

Testing your inhaler

1. When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the cover sides with your thumb and forefinger and pull apart.



2. To make sure that the inhaler works, shake it well, point the mouthpiece away from you and press the canister to release two puffs into the air. If you have not used the inhaler for 5 days or more, shake it well and release two puffs of medicine into the air.

Using your inhaler

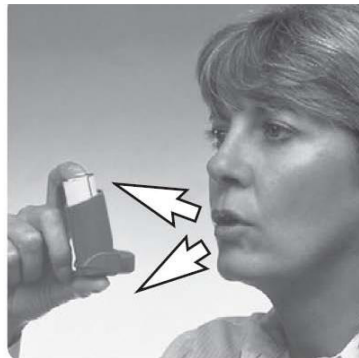
It is important to start to breathe as slowly as possible just before using your inhaler.

1. Stand or sit upright when using your inhaler.
2. Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of foreign objects.

3. Shake the inhaler 4 or 5 times to ensure that any loose foreign objects are removed and that the contents of the inhaler are evenly mixed.



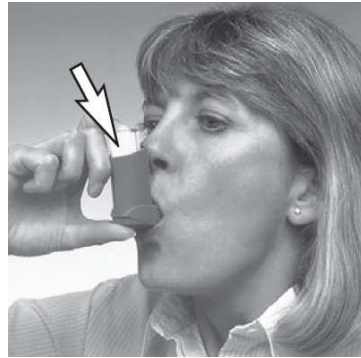
4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as you can. Do not breathe in yet.



5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



6. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.



7. Hold your breath, remove the inhaler from your mouth and your finger from the top of the canister. Continue holding your breath for a few seconds, or as long as you can.



8. If your physician has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

9. After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth, you should start again.

Young children may need help of their parents to operate the inhaler. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together. You may find an adapter (spacer), with or without a face mask, useful if you have to give Ventolin Inhaler to a baby or a child under the age of 5. Speak to your physician if you think you might need one of these.

Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the canister and both thumbs below the mouthpiece. If this does not help, your physician, nurse or pharmacist will be able to advise you.

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 the mouthpiece cover.

Do not put the metal canister in water.

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