

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

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

Ventolin Diskus

Powder for Inhalation

Each metered dose contains:

salbutamol (as sulfate) 200 mcg

Ventolin Diskus contains 60 metered doses.

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 Diskus is used to treat breathing problems in people with asthma and similar conditions. This includes relieving and preventing asthma brought on by exercise or other “triggers”, such as dust, pollen, cats, dogs and cigarette smoke.

Therapeutic group:

Selective beta-2 adrenoceptor agonist.

Ventolin Diskus 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.

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).
- you are allergic to lactose or milk protein.

Special warnings regarding use of the medicine

Before the treatment with Ventolin Diskus, 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. Remember to take this medicine with you if you have to go to hospital. In particular tell your physician or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat (especially medicines of the beta blockers group, such as propranolol).
- other medicines for your asthma.

Using the medicine and food

You can use Ventolin Diskus 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

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

Important information about some of the ingredients in the medicine

This medicine contains lactose monohydrate. If you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicinal product.

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 children:

- for immediate relief of asthma - one inhalation (200 micrograms).
- in chronic treatment - one inhalation (200 micrograms) up to 4 times a day.
- to prevent asthma due to exercise or allergen exposure - one inhalation (200 micrograms) 10 to 15 minutes before allergen exposure or exercise.
- the maximum dose is one inhalation (200 micrograms) four times a day.

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 have used a dosage higher 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 the medicine, immediately contact a physician or go to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine

- If you forgot a dose of the medicine, 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 using Ventolin Diskus 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 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 Diskus 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 Diskus and contact 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 effects may affect **up to 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 with 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 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.

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, contact 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 Diskus 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.
- Do not store above 30°C. Store in the original package.
- If you are told to stop taking this medicine, return the medicine 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: lactose monohydrate (contains milk protein).
- What the medicine looks like and the contents of the package:
Ventolin Diskus contains 60 metered doses of 200 micrograms of salbutamol (as sulfate).
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithkline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 126-97-30674.

Instructions for use:

- Your physician or pharmacist should show you how to use your Diskus. They should check how you use it from time to time. Not using Ventolin Diskus properly or as prescribed may mean that it will not help your asthma as it should.

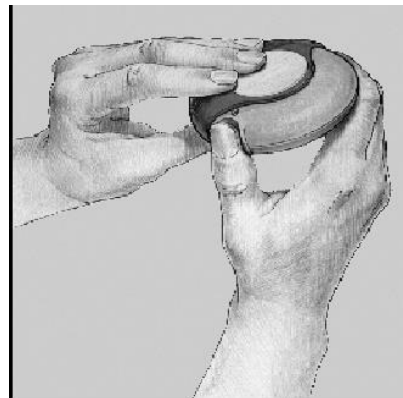
- The Ventolin Diskus device contains blisters containing Ventolin as a powder.
- There is a counter on top of the Ventolin Diskus, which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your Diskus is empty.

Do not use your Diskus 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.

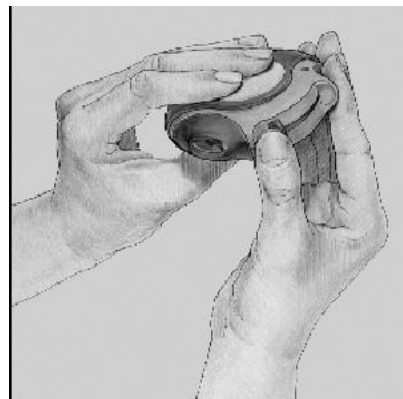
Your physician may have told you to use more than the usual dose as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you follow your physician's instructions as to how many inhalations to take and how often to use your Diskus.

Using your Diskus

1. To open the Ventolin Diskus, hold the outer case in one hand and put the thumb of your other hand on the thumb grip. Push your thumb away from you as far as it will go. You will hear a click. This will open a small hole in the mouthpiece.



2. Hold the Ventolin Diskus with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of the medicine in the mouthpiece.



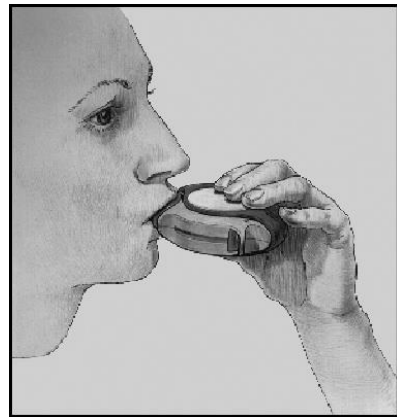
Every time the lever is pushed back, a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever, as this opens the blisters and wastes medicine.

3. Hold the Ventolin Diskus away from your mouth, breathe out as far as you can. Do not breathe into the Ventolin Diskus. Do not breathe in again yet.

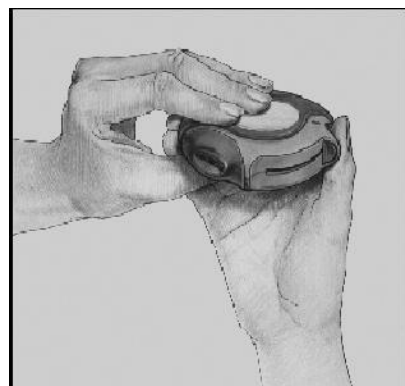
4. Put the mouthpiece to your lips; breathe in steadily and deeply through the Ventolin Diskus with your mouth, not through your nose. Remove the Ventolin Diskus from your mouth.

Hold your breath for about 10 seconds or for as long as you can.

Breathe out slowly.



5. To close the Ventolin Diskus, slide the thumb grip back towards you, as far as it will go. You will hear a click. The lever will return to its original position and will be reset. The Diskus is now ready for you to use again.



Cleaning your Diskus

Wipe the mouthpiece of the Diskus with a dry tissue to clean it.

Revised in October 2023 according to MoH guidelines.

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