

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

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

Ventolin™ Diskus™

Each dose contains 200 micrograms salbutamol (as sulfate) inhalation powder

Ventolin Diskus contains 60 measured doses.

List of the additional ingredients listed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not give it to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

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

Therapeutic group: β_2 adrenoceptor agonist.

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 the medicine as listed in section 6.
- you unexpectedly go into early labour (premature labour) or threatened abortion.
- you have a severe milk-protein allergy.

Special warnings regarding the use of the medicine

Talk to your physician or pharmacist before taking Ventolin Diskus if:

- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your physician may start or increase the treatment in order 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 water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.

If you are taking, have recently taken or might take other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. Don't forget to take this medicine with you if you have to go to hospital. Especially inform the physician or the pharmacist if you are taking:

- medicines for an irregular or fast heartbeat (especially from 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, 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 physician or pharmacist for advice before taking this medicine.

Driving and using machines

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

Important information about some ingredients of the medicine

This medicine contains lactose. 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 according to the physician's instructions.

You should check with the physician or the pharmacist if you are unsure.

The dosage and treatment will be determined only by the physician. The usual dosage is:

Adults and children:

For immediate relief, one inhalation (200 micrograms).

For chronic treatment, one inhalation (200 micrograms) up to 4 times a day.

For prevention as a result of physical activity or exposure to an allergen, one inhalation (200 micrograms), 10-15 minutes before the exposure or the physical activity.

The maximum dose is one inhalation (200 micrograms) 4 times a day.

Do not exceed the recommended dose

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

If you accidentally have taken a higher dosage 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 forgot to take the medicine

- If you forget a dose, 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.

Persist with the treatment as recommended by the physician.

If you stop taking the medicine

Do not stop taking Ventolin Diskus without talking to 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 the use of the medicine, consult the physician or the 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 of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

The following side effects may happen with this medicine:

Allergic Reactions (very rare, may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking Ventolin 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 light-headed, and collapse.

Refer to the 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 may affect up to 1 in 10 people (common).

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 (may affect up to 1 in 10 people)

- feeling shaky
- headache.

Uncommon side effects (may affect up to 1 in 100 people)

- mouth and throat irritation
- muscle cramps.

Rare side effects (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 (may affect up to 1 in 10,000 people)

- changes in sleep patterns and changes in behavior, such as restlessness and excitability (hyperactivity).

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 physician or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

If a side effect has appeared, if any of the side effects gets worse or when you suffer from side effect not mentioned in the leaflet, you should consult the physician.

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 Diskus unless your physician tells you to.

Adverse Reactions Reporting

Adverse events can be reported to the Ministry of Health via the on-line form for adverse events reporting, that is located on the Ministry of Health home page www.health.gov.il or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep in the original package.

6. Additional information

- In addition to the active ingredient the medicine also contains: lactose monohydrate.
- What does the medicine look like and what is the content of the package: Ventolin Diskus contains 60 doses of 200 micrograms of salbutamol (as sulfate).
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Wellcome Production, Evreux, France.
- This leaflet was checked and approved by the Ministry of Health in: August 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health 126-97-30674

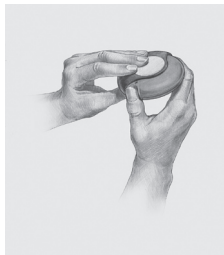
Instructions for use:

- Your physician or pharmacist will show you how to use your diskus. They will check how you use it from time to time. Not using the Ventolin Diskus properly or as prescribed may mean that it will not help your asthma as it should.
- The Ventolin Diskus device holds 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 take more than the usual dose as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your physician's instructions as to how many inhalations to take and how often to use your diskus.

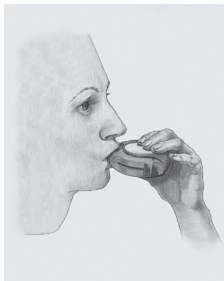
Using your Diskus



- To open the Ventolin Diskus, hold the outer case in one hand and put the thumb of your other hand on the thumbgrip. 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.



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



- Hold the Ventolin Diskus away from your mouth; breathe out as far as is comfortable. Do not breathe out into your Ventolin Diskus. Do not breathe in yet.

- 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 is comfortable. Breathe out slowly.



- To close the Ventolin Diskus, slide the thumbgrip back towards you until you will hear a click. The lever will return to its original position and is reset. Your 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.