

Package leaflet: Information for the user

Ventolin Diskus 200 micrograms/dose - inhalation powder, pre-dispensed

salbutamol

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Ventolin Diskus 200 and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

#### 1. What is Ventolin Diskus and what is it used for?

Ventolin Diskus 200 contains the active substance salbutamol. Salbutamol belongs to a group of medicines called short-acting bronchodilators (effect lasts about 4-6 hours). Short-acting bronchodilators relax the muscles in the walls of the small air passages in the lungs within minutes. Ventolin Diskus 200:

helps keep the airways in the lungs open, making it easier to breathe in and out  
relieves the tight feeling in the chest and reduces wheezing and coughing associated with asthma

Ventolin Diskus 200 is used to treat breathing problems in people with asthma and similar conditions. The effect also includes relief and prevention of asthma symptoms due to exercise (exercise-induced asthma) and other factors that promote asthma. Other factors include house dust, pollen, cats, dogs, and cigarette smoke.

#### 2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

→ If you think this applies to you, do not use this medicine until you have consulted your doctor.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine. Before using this medicine, your doctor needs to know the following:

- if you have high blood pressure
  - if you have an overactive thyroid
  - if you have a history of heart problems such as an irregular or fast heartbeat or angina (chest pain)
  - if you have low potassium levels in your blood
  - if you are using xanthine derivatives (such as theophylline) or steroids for the treatment of asthma
  - if you are using diuretics. These are sometimes used for the treatment of high blood pressure or other heart conditions
- Your doctor will measure your potassium levels if you are using xanthine derivatives, steroids, or diuretics.
- Ask your doctor for advice if you think any of these points apply to you.

Ventolin Diskus should be used as needed rather than regularly.

If your asthma is active (you often have symptoms or flare-ups, such as shortness of breath that makes talking, eating, or sleeping difficult, coughing, wheezing, a feeling of tightness in the chest, or your physical ability is limited), tell your doctor immediately. Your doctor may advise you to start or increase the use of an asthma control medication, such as an inhaled corticosteroid.

Increasing use of a bronchodilator such as salbutamol may be a sign of worsening asthma. Tell your doctor as soon as possible if your medication no longer seems to work as usual (for example, if you need more inhalations to relieve your breathing problems or if using your inhaler provides relief for less than 3 hours), as this may indicate that your airway symptoms are worsening and you may need another medication.

If you use Ventolin Diskus more than twice a week to treat your asthma symptoms, not counting prevention of exercise-induced asthma, it is a sign that your asthma is not well controlled. This can increase the risk of severe asthma attacks (worsening of asthma), which can have serious consequences and be life-threatening or even fatal. Contact your doctor as soon as possible so that your asthma treatment can be reviewed.

Do you use a daily medication for inflammation of your lungs, such as a 'inhaled corticosteroid'? Then it is important that you continue to use that medication regularly, even if you feel better.

Reports of tooth decay (caries) have been reported with the use of salbutamol. It is recommended to pay attention to good oral hygiene and regular dental check-ups, especially in children.

Are you using any other medications?

Are you using any other medications in addition to Ventolin Diskus 200, or have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your doctor or pharmacist.

Some medications can affect the action of Ventolin Diskus 200, or make it more likely that you will experience side effects. These include:

beta-blockers (such as propranolol, a group of medications used to treat high blood pressure or a heart condition)

→ Your doctor or pharmacist will decide whether you can use Ventolin Diskus 200 with these medications.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication. Your doctor will determine whether you can use Ventolin Diskus 200 during pregnancy and breastfeeding.

Driving and using machines

It is unlikely that Ventolin Diskus 200 affects the ability to drive and use machines.

Ventolin Diskus 200 contains lactose

Ventolin Diskus 200 contains up to 40 milligrams of lactose per dose. If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before using this medicine.

The excipient lactose contains small amounts of milk proteins which could cause an allergic reaction.

### 3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage is:

Adults and adolescents (12 years and older):

for relief of asthma - the usual starting dose is 1 inhalation (200 micrograms) once a day as needed. Maximum daily dose: 800 micrograms (4 inhalations), as needed  
for prevention of exercise-induced asthma - 1 inhalation (200 micrograms) 10 to 15 minutes before exercise

Children (4 to 11 years):

for relief of asthma - the usual starting dose is 1 inhalation (200 micrograms) once a day as needed  
for prevention of exercise-induced asthma - 1 inhalation (200 micrograms) 10 to 15 minutes before exercise  
as needed – the usual starting dose is 1 inhalation (200 micrograms) four times a day

The maximum daily dose is 1 inhalation (200 micrograms), four times a day. Do not use more inhalations at a time or use your Diskus more frequently. Tell your doctor if your medicine no

longer seems to work as well as usual, as this may indicate that your respiratory symptoms are worsening and you may need another medicine.

If you are using another inhaler, your doctor may adjust the dosage. Always do this in consultation with your doctor.

If you use Ventolin for asthma, your doctor will want to regularly check your symptoms.

#### Instructions for correct use

your doctor, nurse, or pharmacist should give you instructions on the correct use of your Diskus. They should regularly check how you use the Diskus. If you do not use the Diskus as prescribed, this may mean that it does not help or is insufficient for the condition for which the Diskus is prescribed. Ventolin Diskus contains blisters with the medicine in powder form. The medicine must be inhaled into your lungs.

#### STEP-BY-STEP INSTRUCTIONS

This section contains the following information:

- Description of your Diskus
- Using your Diskus
- Cleaning your Diskus

#### Description of your Diskus

When you take the Diskus out of the packaging, it is in a closed position. The Diskus contains 60 doses of your medication in powder form. Each dose is individually protected.

At the top of the Diskus is a dose counter, which shows you how many doses are left. It counts down to 0. The numbers 5 to 0 appear in RED to warn you that only a few doses are left. Once the counter reaches 0, your Diskus is empty.

When you want to use a dose, follow the 4 simple steps shown below:

1. Open your Diskus
2. Slide the lever as far back as possible
3. Inhale
4. Close your Diskus

#### Using your Diskus

1. Open your Diskus - To open your Diskus, hold the outer casing of the Diskus in one hand and place the thumb of the other hand on the thumb grip. Push your thumb away from you as far as possible. You will hear a click. This opens a small hole in the mouthpiece.
2. Preparing the dose - Slide the lever as far back as possible. Hold the Diskus with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever as far back as possible. You will hear a click. This places a dose of your medication in the mouthpiece. Each time the lever is pushed back, a blister inside the

Diskus is opened and the powder is ready to be inhaled. Do not play with the lever, as this will open the blisters and medication will be lost.

3. Inhale - Hold the Diskus away from your mouth and breathe out as far as possible. Do not breathe into your Diskus. Place the mouthpiece to your lips and breathe in steadily and deeply through the Diskus and not through your nose. Remove the Diskus from your lips. Hold your breath for about 10 seconds or as long as you can without much discomfort. Breathe out slowly.
4. Close your Diskus - To close the Diskus, slide the thumb grip back towards you as far as possible. You will hear a click. The lever returns to the starting position and is ready for use again. The Diskus can now be used by you again.

### Cleaning your Diskus

Clean the mouthpiece of the Diskus with a dry tissue.

Have you used too much of this medicine?

If you have used too much of this medicine, contact your doctor or pharmacist for advice. If possible, take the Ventolin Diskus 200 packaging with you.

Have you forgotten to use this medicine?

If you forget to inhale your medicine, take the next dose as scheduled. Do not take a double dose to make up for a forgotten dose.

If you experience wheezing or other symptoms of an asthma attack, it may be necessary to take the next dose earlier.

If you stop using this medicine

Use this medicine for as long as your doctor has prescribed. You should only stop using it on your doctor's advice.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

### 4. Possible side effects

If your breathing worsens immediately after using the medicine (known as paradoxical bronchospasm), stop using it immediately and contact your doctor as soon as possible. If available, try another short-acting asthma medicine as soon as possible.

Like all medicines, this medicine can cause side effects, although not everyone gets them.

### Conditions where you need to be cautious

Allergic reactions: these are very rare in patients using Ventolin Diskus 200.

Symptoms include:

- skin rash (hives) and redness
- swelling, sometimes of the face or mouth (angioedema)
- wheezing, coughing, or breathing problems

suddenly feeling weak or lightheaded. This can lead to fainting or loss of consciousness (collapse)

→ Contact your doctor immediately if you experience any of these symptoms. Stop using this medicine.

The following side effects have been reported with the use of Ventolin Diskus 200.

Common: occur in less than 1 in 10 patients:

- tremor
- headache
- increased heart rate (tachycardia)

Sometimes: occur in less than 1 in 100 patients:

- irregular heartbeat (palpitations)
- muscle cramps
- irritation of the mouth and throat

Rare: occur in less than 1 in 1,000 patients:

- low potassium levels in the blood (hypokalemia)
- increased blood flow to the limbs (arms, legs) due to dilation of the blood vessels (peripheral vasodilation)

Very rare: occur in less than 1 in 10,000 patients:

- hypersensitivity reactions (allergic reactions; see above)
- hyperactivity, such as restlessness and irritability
- arrhythmias

Unknown: based on available data, the frequency cannot be determined

- oxygen deficiency of the heart muscle (myocardial ischemia)

Although it is not exactly known how often it occurs, some people may occasionally feel chest pain. This pain may be caused by heart problems. Inform your doctor (or if you are pregnant, your midwife) if you experience such symptoms while using salbutamol. Do not stop using salbutamol on your own, only do so if advised by your doctor.

- tooth decay (caries)

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How should you store this medicine?

Keep out of the sight and reach of children.

Store below 30 °C in the original packaging (to protect from light and freezing).

Do not use this medicine after the expiry date. This can be found on the box and on the Diskus after the text: "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is salbutamol
- The other substance in this medicine is lactose (contains milk protein)

What does Ventolin Diskus 200 look like and how much is in a package?

Ventolin Diskus 200 contains a foil strip. The foil protects the inhalation powder from atmospheric influences  
each dosage is pre-measured  
the Diskus is packed in a cardboard box and the Diskus contains 60 inhalations of 200 micrograms of salbutamol each (as salbutamol hemisulfate)  
the Diskus has a dose counter

Marketing authorization holder and manufacturer

Marketing authorization holder  
GlaxoSmithKline BV  
Van Asch van Wijckstraat 55H  
3811 LP Amersfoort  
033 2081100

Manufacturer  
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Ventolin Diskus 200 is registered in the Netherlands under number RVG 19496

This leaflet was last approved in March 2024.

More information about this medicine is available on the website of the Medicines Evaluation Board: [www.cbg-meb.nl](http://www.cbg-meb.nl).