GSK logo

Package Leaflet: Information for the User

Ventolin Diskus 200 micrograms Inhalation Powder, pre-dispensed

salbutamol (as sulfate)

[Product Picture with part descriptions]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Ventolin Diskus is and what it is used for
2. What you need to know before you use Ventolin Diskus
3. How to use Ventolin Diskus
4. Possible side effects
5. How to store Ventolin Diskus
6. Contents of the pack and other information

What Ventolin Diskus is and what it is used 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 adults, adolescents and children over 4 years of age with asthma and other conditions such as chronic bronchitis and emphysema. This includes relieving and preventing asthma brought on by exercise or other “triggers”. These are things, which bring on asthma symptoms in some people. Common triggers include house dust, pollen, cats, dogs and cigarette smoke.

What you need to know before you use Ventolin Diskus

Do not use Ventolin Diskus:

- if you are allergic to salbutamol sulfate or the other ingredient lactose (contains milk protein).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Ventolin Diskus if:

- you have high blood pressure
- you have an overactive thyroid gland
- you have a history of heart problems such as, severe heart failure, an irregular

or fast heartbeat or angina
- You suffer from acute severe asthma (your doctor may need to carry out blood tests to monitor the amount of potassium in your blood)
- you have diabetes (high blood sugar levels)

If your asthma or breathing gets worse tell your doctor straight away. Your chest condition may be getting worse and you could become seriously ill.

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

Children
An adult should supervise use of the Diskus in children.

Other medicines and Ventolin Diskus
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.

In particular, tell your doctor, nurse or pharmacist if you are taking:
- medicines for an irregular or fast heartbeat e.g. propranolol
- other medicines for your asthma
- medicines used to treat high blood pressure e.g. guanethidine and methyldopa
- reserpine (used to treat high blood pressure or severe agitation)
- tricyclic antidepressants
- diuretics, steroids and xanthine derivatives
- anaesthetics such as chloroform, cyclopropane and halothane

Tell your doctor that you are taking Ventolin if you are going to have an operation as it may interact with some anaesthetics.

Pregnancy, breast-feeding and fertility. If you are pregnant or breast-feeding, think you may be pregnant or are planning a baby, ask your doctor 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.

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

How to use Ventolin Diskus

Always use your Ventolin Diskus exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Adults, Adolescents and Children over 4 years of age
- to relieve asthma - One inhalation (200 micrograms).
- to prevent asthma - One inhalation (200 micrograms) 10 to 15 minutes before exercise or exposure to a “trigger”.
- long term treatment - One inhalation (200 micrograms) up to four times a day.

- the maximum dose is one inhalation (200 micrograms) four times a day.

Instructions for use

- Your doctor, nurse or pharmacist should show you how to use your Diskus. They should 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.

Ventolin Diskus should be used as required rather than regularly.

If your asthma is active (for example you have frequent symptoms or flare ups, such as breathlessness that makes speaking, eating or sleeping difficult, cough, wheezing, tight chest or limited physical ability), you should tell your doctor right away who may start or increase a medicine to control your asthma such as an inhaled corticosteroid.

Do not use your Diskus more often than the doctor told you to.

Tell your doctor **promptly** if your medicine does not seem to be working as well as usual **(for example you need higher doses to relieve your breathing problems or your inhaler fails to give rapid relief with a duration of at least 3 hours following administration)** as your chest problem may be getting worse and you may need a different medicine.

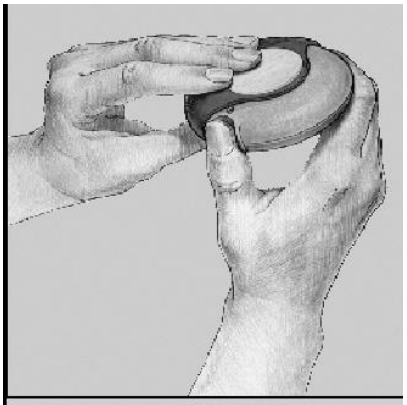
If you use Ventolin Diskus more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many blisters to take and how often to use your Diskus.

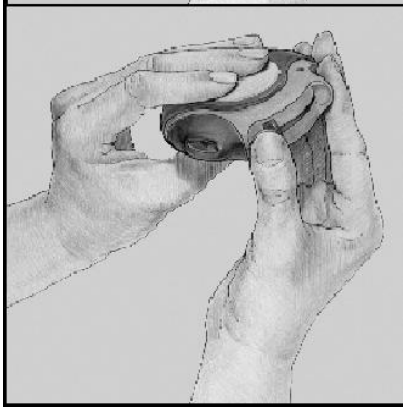
Using your Diskus

1 To open your 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.



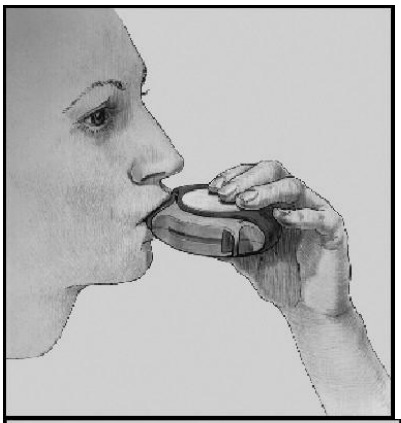
2 Hold your Ventolin Diskus with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece.

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

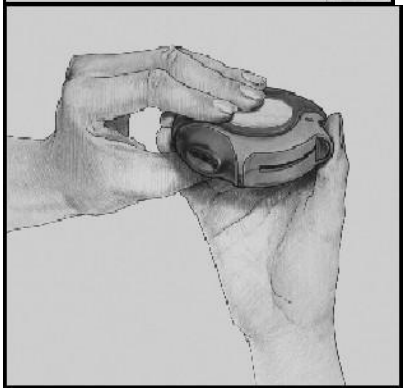


3 Hold the Ventolin Diskus away from your mouth, breathe out as far as is comfortable. Do not breathe into your Ventolin Diskus. Do not breathe in again yet.

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 is comfortable.
Breathe out slowly.



5 To close the Ventolin Diskus, slide the thumbgrip back towards you, as far as it will go. 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.

If you use more Ventolin Diskus than you should
If you use more than you should, talk to a doctor as soon as possible.
The following effects may happen:

- your heart beats faster than usual
- you feel shaky
- hyperactivity
- acid builds up in your body which may cause your breathing to become faster.

These effects usually wear off in a few hours.

If you forget to use Ventolin Diskus

- If you forget 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 using Ventolin Diskus
Do not stop using Ventolin Diskus without talking to your doctor.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

Possible side effects

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

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic Reactions (may affect up to 1 in 10,000 people)
If you have an allergic reaction, stop taking Ventolin and see a doctor 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 doctor 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 doctor as soon as possible. **Do not stop using this medicine unless told to do so**.

Tell your doctor if you have any of the following side effects which may also happen with this medicine:
Common (may affect up to 1 in 10 people)

- feeling shaky
- headache.

Uncommon (may affect up to 1 in 100 people)

- mouth and throat irritation

- muscle cramps.

Rare (may affect up to 1 in 1,000 people)
- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral vasodilatation).

Very rare (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 are not known:
- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

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 doctor 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 doctor tells you to.

How to store Ventolin Diskus

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Protect from frost and sunlight.
- Do not use Ventolin Diskus after the expiry date, which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.
- If you are told to stop taking this medicine return any unused Ventolin Diskus to your pharmacist to be destroyed.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Contents of the pack and other information

What Ventolin Diskus contains
- The active substance is salbutamol (as sulfate).
- The other ingredient is lactose monohydrate (contains milk protein).
- Each blister contains 200 micrograms of salbutamol (as sulfate).

What Ventolin Diskus looks like and contents of the pack
Ventolin Diskus contains a foil strip. The foil protects the powder for inhalation from the effects of the atmosphere.
Each dose is pre-dispensed.
Each inhaler contains 60 doses of 200 micrograms of salbutamol (as sulfate).

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