

**PART III: CONSUMER INFORMATION****Pr**VENTOLIN DISKUS  
salbutamol sulfate powder for oral inhalation

This leaflet is part III of a three-part "Product Monograph" for VENTOLIN DISKUS and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VENTOLIN DISKUS. Please read this leaflet carefully before you start to take your medicine or start administering it to a child. Contact your doctor or pharmacist if you have any questions about the drug. This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

**ABOUT THIS MEDICATION****What the medication is used for:**

VENTOLIN DISKUS is used in Adults and Children 4 years or older to:

- relieve bronchospasm
- prevent bronchospasm
- prevent bronchospasm caused by exercise

Bronchospasm is a sudden worsening of shortness of breath and wheezing.

The safety and effectiveness of VENTOLIN DISKUS in children under the age of 4 are not known.

**What it does:**

Salbutamol is one of a group of medicines called bronchodilators. Salbutamol relaxes the muscles in the walls of the small air passages in the lungs. This helps to open up the airways and so helps to relieve chest tightness, wheezing and cough so that you can breathe more easily.

**When it should not be used:**

Do not use VENTOLIN DISKUS if you are allergic to it or any of the components of its formulation including lactose (milk sugar) or milk protein or for the treatment of preterm labour or miscarriage.

**What the medicinal ingredient is:**

Salbutamol sulfate

**What the nonmedicinal ingredients are:**

Lactose (milk sugar which includes milk protein).

**What dosage forms it comes in:**

VENTOLIN DISKUS inhalation powder is a disposable blue-coloured plastic inhaler device containing a foil strip with 60 blisters. Each blister contains 200 mcg of the active ingredient salbutamol (as the sulfate salt). The blisters protect the powder for inhalation from effects of the atmosphere. It cannot be refilled.

**WARNINGS AND PRECAUTIONS**

**Before** you use VENTOLIN DISKUS talk to your doctor or pharmacist if:

- You have ever had to stop taking other medicines for this illness because you were allergic to them or they caused problems.
- You are having treatment for a thyroid condition.
- You are having treatment for high blood pressure or a heart problem.
- You have been told that you are allergic to lactose (milk sugar) or milk protein.
- You have diabetes.
- You have a past history of seizures.
- You have low levels of potassium in your blood (hypokalemia), especially if you are taking:
  - Drugs known as xanthine derivatives (such as theophylline)
  - steroids to treat asthma
  - Water pills (diuretics)
- You are pregnant or intend to become pregnant. Taking VENTOLIN DISKUS during pregnancy may cause harm to your baby. Your doctor will consider the benefit to you and the risk to your baby of taking VENTOLIN DISKUS while you're pregnant
- You are breastfeeding. It is not known if VENTOLIN DISKUS passes into breast milk

If the relief of wheezing or chest tightness is not as good as usual, or the effect lasts for less than three hours, tell your doctor as soon as possible. If you notice a sudden worsening of your shortness of breath and wheeze shortly after taking your medicine, tell your doctor as soon as possible. It may be that your chest condition is worsening and you may need to add another type of medicine to your treatment.

You should always carry your VENTOLIN DISKUS with you to use immediately in case you experience an asthma attack.

**Effects on Children:**

Children may experience:

- Changes in sleep patterns
- changes in behaviour such as restlessness, excitability (hyperactivity)
- seeing or hearing things that are not there

**INTERACTIONS WITH THIS MEDICATION**

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with VENTOLIN DISKUS:

- Anti-depressants
- Allergy medication
- Blood pressure-lowering drugs, including propranolol
- Diuretics (“water pills”)
- Bronchodilators used to open the airway (such as other asthma medication)
- Epinephrine
- Digoxin, a heart medication

## PROPER USE OF THIS MEDICATION

VENTOLIN DISKUS **should only be inhaled**. Do not swallow.

If You Are Also Using an Inhaled Corticosteroid:

- Always use VENTOLIN DISKUS first
- Wait a few minutes
- Then use your inhaled corticosteroid.

Your doctor may prescribe VENTOLIN DISKUS regularly every day, or only for when you are wheezy or short of breath, or before you exercise. Use VENTOLIN DISKUS only as directed by your doctor.

The action of VENTOLIN DISKUS may last up to 6 hours and should last at least 4 hours.

**You should call your doctor immediately if:**

- the effects of one dose last less than 3 hours;
- you notice a sudden worsening of your shortness of breath
- your symptoms gets worse;
- your usual dose does not provide relief of wheezing or chest tightness;
- you need to use VENTOLIN DISKUS more often than before

These may be signs that your asthma or chest condition is getting worse. Your doctor may want to reassess your treatment plan.

**Do not increase the dose or the number of times you use your medicine without asking your doctor, as this may make you feel worse.**

If you have to go to hospital for an operation, take VENTOLIN DISKUS with you and tell the doctor what medicine(s) you are taking.

Usual dose:

**Adults and Children 4 years or older**

- **To relieve bronchospasm:** 1 inhalation as needed. If you have a more severe attack, you can repeat the dose every 4 to 6 hours, and immediately consult your doctor or the nearest hospital
- **To prevent bronchospasm:** 1 inhalation repeated every 4 to 6 hours up to a maximum three or four times a day as prescribed by your doctor
- **To prevent bronchospasm caused by exercise:** 1 inhalation 15 minutes before exercise

**Maximum dose** - 4 inhalations in a 24 hour period

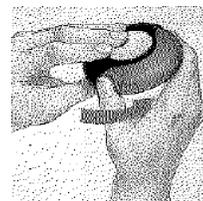
**How to Use VENTOLIN DISKUS:**

VENTOLIN DISKUS is closed when you first take it out of the box. It counts down from 60 to 1. **To show when the last five doses have been reached the numbers appear in red.**

Before you use VENTOLIN DISKUS read through this entire section carefully.

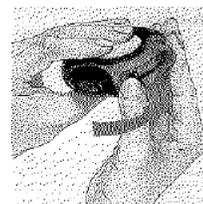
### 1. Open

To open your DISKUS inhaler 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.



### 2. Slide

Hold your DISKUS inhaler with the mouthpiece towards you. Slide the lever away from you as far as it will go – until it clicks. Your DISKUS inhaler is now ready to use. Every time the lever is pushed back a dose is made available for inhaling. This is shown by the dose counter. Do not play with the lever as this releases dose which will be wasted.



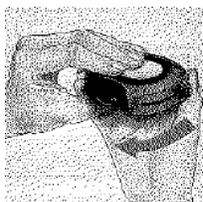
### 3. Inhale

- Hold the DISKUS inhaler away from your mouth. Breathe out as far as is comfortable. Remember – never breathe into your DISKUS inhaler.
- Put the mouthpiece to your lips. Breathe in steadily and deeply – through the DISKUS inhaler, not through your nose.
- Remove the DISKUS inhaler from your mouth.
- Hold your breath for about 10 seconds or for as long as is comfortable.
- Breathe out slowly.



**4. Close**

To close your DISKUS inhaler, put your thumb in the thumb grip, and slide the thumb grip back towards you, as far as it will go.



When you close the DISKUS inhaler, it clicks shut. The lever automatically returns to its original position and is reset. Your DISKUS inhaler is now ready for you to use again.

**Remember:**

Keep your DISKUS inhaler dry.

Keep it closed when not in use.

Only slide the lever when you are ready to take a dose.

**Children** - During inhalation, children should be assisted or supervised by an adult who knows the proper use of the inhaler.

**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Take this leaflet or your medication with you so that the hospital or poison control centre will know what you have taken.

If you accidentally take a **larger dose than prescribed**, you are more likely to get side effects like a faster heart beat, headaches and feeling shaky or restless. These effects usually wear off within a few hours, but you should tell your doctor as soon as possible.

**Missed Dose:**

If you forget to inhale a dose do not worry, just inhale the next dose when it is due or if you become wheezy. Your doctor may have told you to use your DISKUS inhaler regularly every day, or only when you are wheezy or short of breath.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Side effects may include:

Effects on heart

- Hypertension

Effects on nervous system

- Headache
- Feeling a little shaky
- Feeling anxious or irritable
- Feeling tired or weak
- Trouble sleeping (insomnia)
- Hyperactivity in children
- Dizziness, vertigo
- Drowsiness

Effects on muscles and joints

- Muscle cramps
- Muscle pain

Other Effects

- Fever
- Respiratory infections and/or inflammation
- Nausea and vomiting
- Chest pain or discomfort
- Flushing
- Difficulty urinating
- Unusual taste in your mouth
- Dry or irritated throat

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Faster heart beat than usual		✓	
Uncommon	Irregular heart beat (palpitations)		✓	
Rare	Low Blood Potassium (hypokalemia): muscle weakness and muscle spasms		✓	
	Hallucinations in Children: see or hear things that are not there		✓	
Very Rare	Bronchospasm: Sudden worsening of shortness of breath and wheezing shortly after using VENTOLIN DISKUS			✓
	Allergic Reactions: sudden wheeziness and chest pain or tightness; or swelling of eyelids, face, lips, tongue or throat.			✓
	Irregular Heart Beat (atrial fibrillation, supraventricular tachycardia, extrasystoles)		✓	

*This is not a complete list of side effects. If you have any unexpected effects after receiving VENTOLIN DISKUS, contact your doctor or pharmacist.*

**HOW TO STORE IT**

**Keep out of sight and reach of children.**

Do not store VENTOLIN DISKUS inhalation powder above 30°C. Keep in a dry place.

Protect from frost and light.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 1908C  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

You may need to read this leaflet again. **PLEASE DO NOT THROW IT AWAY** until you have finished your medicine.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca>

or by contacting the sponsor, GlaxoSmithKline Inc.  
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Mississauga, Ontario  
L5N 6L4  
1-800-387-7374

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