

MEDICATION GUIDE

SEREVENT[®] [*ser' uh-vent*] DISKUS[®] (salmeterol xinafoate inhalation powder)

Read the Medication Guide that comes with SEREVENT DISKUS before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about SEREVENT DISKUS?

SEREVENT DISKUS can cause serious side effects, including:

- 1. People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines such as salmeterol (SEREVENT DISKUS), have an increased risk of death from asthma problems.**
 - Call your healthcare provider if breathing problems worsen over time while using SEREVENT DISKUS. You may need a different treatment.
 - Get emergency medical care if:
 - breathing problems worsen quickly, and
 - you use your rescue inhaler medicine, but it does not relieve your breathing problems.
- 2. Do not use SEREVENT DISKUS as your only asthma medicine. SEREVENT DISKUS must only be used with a long-term asthma-control medicine, such as an inhaled corticosteroid.**
3. When your asthma is well controlled, your healthcare provider may tell you to stop taking SEREVENT DISKUS. Your healthcare provider will decide if you can stop SEREVENT DISKUS without loss of asthma control. You will continue taking your long-term asthma-control medicine, such as an inhaled corticosteroid.
4. Children and adolescents who take LABA medicines may have an increased risk of being hospitalized for asthma problems.

What is SEREVENT DISKUS?

- SEREVENT DISKUS is a LABA medicine. LABA medicines help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe. In severe cases, wheezing can stop your breathing and cause death if not treated right away.
- SEREVENT DISKUS is used for asthma, exercise-induced bronchospasm (EIB), and chronic

obstructive pulmonary disease (COPD) as follows:

Asthma:

SEREVENT DISKUS is used in adults and children aged 4 years and older, with a long-term asthma control medicine, such as an inhaled corticosteroid:

- to control symptoms of asthma, and
- to prevent symptoms such as wheezing.

LABA medicines, such as SEREVENT DISKUS, increase the risk of death from asthma problems. SEREVENT DISKUS is not for adults and children with asthma who are well controlled with a long-term asthma-control medicine, such as a low to medium dose of an inhaled corticosteroid medicine.

Exercise-Induced Bronchospasm:

SEREVENT DISKUS is used to prevent wheezing caused by exercise in adults and children aged 4 years and older.

- If you have EIB only, your healthcare provider may prescribe only SEREVENT DISKUS for your condition.
- If you have EIB and asthma, your healthcare provider should also prescribe an asthma control medicine, such as an inhaled corticosteroid.

Chronic Obstructive Pulmonary Disease:

SEREVENT DISKUS is used long term, 2 times each day (morning and evening) to control symptoms of COPD and prevent wheezing in adults with COPD.

Who should not use SEREVENT DISKUS?

Do not take SEREVENT DISKUS:

- to treat your asthma without an asthma medicine known as an inhaled corticosteroid
- if you are allergic to salmeterol or any of the ingredients in SEREVENT DISKUS. Ask your healthcare provider if you are not sure. See the end of this Medication Guide for a complete list of ingredients in SEREVENT DISKUS.

What should I tell my healthcare provider before using SEREVENT DISKUS?

Tell your healthcare provider about all of your health conditions, including if you:

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- have liver problems

- are pregnant or planning to become pregnant. It is not known if SEREVENT DISKUS may harm your unborn baby.
- are breastfeeding. It is not known if SEREVENT DISKUS passes into your milk and if it can harm your baby.
- are allergic to SEREVENT DISKUS, any other medicines, or food products. See the end of this Medication Guide for a complete list of ingredients in SEREVENT DISKUS.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. SEREVENT DISKUS and certain other medicines, especially those used to treat infections, may interact with each other. This may cause serious side effects.

Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist each time you get a new medicine.

How do I use SEREVENT DISKUS?

See the step-by-step instructions for using the SEREVENT DISKUS at the end of this Medication Guide. Do not use SEREVENT DISKUS unless your healthcare provider has taught you and you understand everything. Ask your healthcare provider or pharmacist if you have any questions.

- Children should use SEREVENT DISKUS with an adult's help, as instructed by the child's healthcare provider.
- Use SEREVENT DISKUS exactly as prescribed. Do not use SEREVENT DISKUS more often than prescribed.
- For asthma and COPD, the usual dose is 1 inhalation 2 times each day (morning and evening). The 2 doses should be about 12 hours apart.
- For preventing exercise-induced bronchospasm, take 1 inhalation at least 30 minutes before exercise. Do not use SEREVENT DISKUS more often than every 12 hours. Do not use extra SEREVENT DISKUS before exercise if you already use it 2 times each day.
- If you miss a dose of SEREVENT DISKUS, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at one time.
- Do not use a spacer device with SEREVENT DISKUS.
- Do not breathe into SEREVENT DISKUS.
- While you are using SEREVENT DISKUS 2 times each day, do not use other medicines that contain a long-acting beta₂-agonist or LABA for any reason. Ask your healthcare provider or pharmacist for a list of these medicines.

- Do not stop using SEREVENT DISKUS or any of your asthma medicines unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- SEREVENT DISKUS does not relieve sudden symptoms. Always have a rescue inhaler medicine with you to treat sudden symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your healthcare provider to have one prescribed for you.
- Call your healthcare provider or get medical care right away if:
 - your breathing problems worsen with SEREVENT DISKUS
 - you need to use your rescue inhaler medicine more often than usual
 - your rescue inhaler medicine does not work as well for you at relieving symptoms
 - you need to use 4 or more inhalations of your rescue inhaler medicine for 2 or more days in a row
 - you use 1 whole canister of your rescue inhaler medicine in 8 weeks' time
 - your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.
 - you have asthma and your symptoms do not improve after using SEREVENT DISKUS regularly for 1 week.
 - after a change in your asthma medicines you have any worsening of your asthma symptoms or an increase in the need for your rescue inhaler medicine.

What are the possible side effects with SEREVENT DISKUS?

SEREVENT DISKUS can cause serious side effects, including:

- **See “What is the most important information I should know about SEREVENT DISKUS?”**
- **serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following symptoms of a serious allergic reaction:
 - rash
 - hives
 - swelling of the face, mouth, and tongue
 - breathing problems.
- **sudden breathing problems immediately after inhaling your medicine**
- **effects on heart**
 - increased blood pressure
 - a fast and irregular heartbeat
 - chest pain
- **effects on nervous system**
 - tremor
 - nervousness

- **changes in blood (sugar, potassium)**

Common side effects of SEREVENT DISKUS include:

Asthma in adults and children:

- headache
- nasal congestion
- bronchitis
- throat irritation
- runny nose
- flu

Chronic obstructive pulmonary disease:

- headache
- musculoskeletal pain
- throat irritation
- cough
- respiratory infection

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects with SEREVENT DISKUS. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store SEREVENT DISKUS?

- Store SEREVENT DISKUS at room temperature between 68°F to 77° F (20°C to 25° C). Keep in a dry place away from heat and sunlight.
- Safely discard SEREVENT DISKUS 6 weeks after you remove it from the foil pouch, or after the dose indicator reads “0”, whichever comes first.
- Keep SEREVENT DISKUS and all medicines out of the reach of children.

General Information about SEREVENT DISKUS

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use SEREVENT DISKUS for a condition for which it was not prescribed. Do not give your SEREVENT DISKUS to other people, even if they have the same condition that you have. It may harm them.

This Medication Guide summarizes the most important information about SEREVENT DISKUS. If you would like more information, talk with your healthcare provider or pharmacist.

You can ask your healthcare provider or pharmacist for information about SEREVENT DISKUS that was written for healthcare professionals. You can also contact the company that makes SEREVENT DISKUS (toll free) at 1-888-825-5249 or at www.serevent.com.

What are the ingredients in SEREVENT DISKUS?

Active ingredient: salmeterol xinafoate

Inactive ingredient: lactose (contains milk proteins)

Instructions for Using SEREVENT DISKUS

Follow the instructions below for using your SEREVENT DISKUS. **You will breathe in (inhale) the medicine from the DISKUS.** If you have any questions, ask your healthcare provider or pharmacist.



Take the SEREVENT DISKUS out of the box and foil pouch. Write the **“Pouch opened”** and **“Use by”** dates on the label on top of the DISKUS. **The “Use by” date is 6 weeks from date of opening the pouch.**

- The DISKUS will be in the closed position when the pouch is opened.
- The **dose indicator** on the top of the DISKUS tells you how many doses are left. The dose indicator number will decrease each time you use the DISKUS. After you have used 55 doses from the DISKUS, the numbers 5 to 0 will appear in **red** to warn you that there are only a few doses left (*see Figure 1*).



Figure 1

Taking a dose from the DISKUS requires the following 3 simple steps: Open, Click, Inhale.

1. OPEN

Hold the DISKUS 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 until the mouthpiece appears and snaps into position (*see Figure 2*).



Figure 2

2. CLICK

Hold the DISKUS in a level, flat position with the mouthpiece towards you. Slide the **lever** away from you as far as it will go until it **clicks** (*see Figure 3*). The DISKUS is now ready to use.



Figure 3

Every time the **lever** is pushed back, a dose is ready to be inhaled. This is shown by a decrease in numbers on the dose counter. **To avoid releasing or wasting doses once the DISKUS is ready:**

- **Do not close the DISKUS.**
- **Do not tilt the DISKUS.**
- **Do not play with the lever.**
- **Do not move the lever more than once.**

3. INHALE

Before inhaling your dose from the DISKUS, breathe out (exhale) fully while holding the DISKUS level and away from your mouth (*see Figure 4*). **Remember, never breathe out into the DISKUS mouthpiece.**



Figure 4

Put the mouthpiece to your lips (*see Figure 5*). Breathe in quickly and deeply through the

DISKUS. Do not breathe in through your nose.



Figure 5

Remove the DISKUS from your mouth. Hold your breath for about 10 seconds, or for as long as is comfortable. Breathe out slowly.

The DISKUS delivers your dose of medicine as a very fine powder. Most patients can taste or feel the powder. Do not use another dose from the DISKUS if you do not feel or taste the medicine.

- 4. Close the DISKUS when you are finished taking a dose so that the DISKUS will be ready for you to take your next dose.** Put your thumb on the thumbgrip and slide the thumbgrip back towards you as far as it will go (*see Figure 6*). The DISKUS will click shut. The lever will automatically return to its original position. The DISKUS is now ready for you to take your next scheduled dose, due in about 12 hours. (Repeat steps 1 to 4.)



Figure 6

Remember:

- Never breathe into the DISKUS.
- Never take the DISKUS apart.
- Always ready and use the DISKUS in a level, flat position.
- Do not use the DISKUS with a spacer device.
- Never wash the mouthpiece or any part of the DISKUS. **Keep it dry.**
- Always keep the DISKUS in a dry place.
- Never take an extra dose, even if you did not taste or feel the medicine.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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