**Treatment of Exercise-Induced Bronchospasm:** Patients using SEREVENT DISKUS for the treatment of EIB should not use additional doses for 12 hours. Patients who are receiving SEREVENT DISKUS twice daily should not use additional SEREVENT for prevention of EIB.

SEREVENT and DISKUS are registered trademarks of the GSK group of companies.

---

**MEDICATION GUIDE**

**SEREVENT® DISKUS® [ser′ uh-vent disk′ us]**
*(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:

- **People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines, such as salmeterol xinafoate (the medicine in SEREVENT DISKUS), have an increased risk of death from asthma problems.**
- **It is not known if LABA medicines such as salmeterol xinafoate increase the risk of death in people with COPD.**
- **Call your healthcare provider if breathing problems worsen over time while using SEREVENT DISKUS.** You may need different treatment.
• Get emergency medical care if:
  • your breathing problems worsen quickly.
  • you use your rescue inhaler, but it does not relieve your breathing problems.

• 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.

• SEREVENT DISKUS should be used only if your healthcare provider decides that your asthma is not well controlled with a long-term asthma control medicine, such as an inhaled corticosteroid. 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.

• 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 prescription inhaled LABA medicine. LABA medicines such as salmeterol xinafoate help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.

• SEREVENT DISKUS is not used to relieve sudden breathing problems.

• It is not known if SEREVENT DISKUS is safe and effective in children younger than 4 years.

• SEREVENT DISKUS is used for asthma, exercise-induced bronchospasm (EIB), and chronic obstructive pulmonary disease (COPD) as follows:
  
Asthma:

SEREVENT DISKUS is a prescription medicine used to control symptoms of asthma and to prevent symptoms such as wheezing in adults and children aged 4 years and older.

SEREVENT DISKUS contains salmeterol xinafoate. LABA medicines such as salmeterol xinafoate increase the risk of death from asthma problems.

SEREVENT DISKUS is not for adults and children with asthma who are well controlled with an asthma control medicine, such as a low to medium dose of an inhaled corticosteroid medicine.
Exercise-Induced Bronchospasm (EIB):

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

- If you only have EIB, your healthcare provider may only prescribe 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 (COPD):

COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both.

SEREVENT DISKUS is a prescription medicine used long term as 1 inhalation 2 times each day to improve symptoms of COPD for better breathing.

Who should not use SEREVENT DISKUS?

Do not use SEREVENT DISKUS:

- to treat your asthma without a long-term asthma control medicine, such as an inhaled corticosteroid.
- if you have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- if you are allergic to salmeterol xinafoate or any of the ingredients in SEREVENT DISKUS. See “What are the ingredients in SEREVENT DISKUS?” below for a complete list of ingredients.

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 allergic to any of the ingredients in SEREVENT DISKUS, any other medicines, or food products. See “What are the ingredients in SEREVENT DISKUS?” below for a complete list of ingredients.

• have any other medical conditions.

• 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 the medicine in SEREVENT DISKUS passes into your milk and if it can harm your baby

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SEREVENT DISKUS and certain other medicines may interact with each other. This may cause serious side effects. Especially, tell your healthcare provider if you take antifungal or anti-HIV medicines.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use SEREVENT DISKUS?

Read the step-by-step instructions for using SEREVENT DISKUS at the end of this Medication Guide.

• Do not use SEREVENT DISKUS unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.

• 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 of SEREVENT DISKUS 2 times each day. Use SEREVENT DISKUS at the same time each day, about 12 hours apart.

• For preventing exercise-induced bronchospasm, the usual dose is 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 1 time.
• If you take too much SEREVENT DISKUS, call your healthcare provider or go to the nearest hospital emergency room right away if you have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness.

• **Do not use other medicines that contain a LABA for any reason.** Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.

• Do not stop using SEREVENT DISKUS 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 with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.

• Call your healthcare provider or get medical care right away if:
  - your breathing problems get worse.
  - you need to use your rescue inhaler more often than usual.
  - your rescue inhaler does not work as well to relieve your symptoms.
  - you need to use 4 or more inhalations of your rescue inhaler in 24 hours for 2 or more days in a row.
  - you use 1 whole canister of your rescue inhaler in 8 weeks.
  - 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.

**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?"

• **sudden breathing problems immediately after inhaling your medicine**

• **effects on heart**
  - increased blood pressure
  - a fast or irregular heartbeat
  - chest pain

• **effects on nervous system**
  - tremor
  - nervousness
**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 your face, mouth, and tongue
- breathing problems.

**changes in laboratory blood values (sugar, potassium)**

**Common side effects of SEREVENT DISKUS include:**

**Asthma:**
- headache
- nasal congestion
- bronchitis
- throat irritation
- runny nose
- flu

**COPD:**
- 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 should I store SEREVENT DISKUS?**

- Store SEREVENT DISKUS at room temperature between 68°F and 77°F (20°C and 25°C). Keep in a dry place away from heat and sunlight.
- Store SEREVENT DISKUS in the unopened foil pouch and only open when ready for use.
- Safely throw away SEREVENT DISKUS in the trash 6 weeks after you open the foil pouch or when the counter 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.

For more information about SEREVENT DISKUS, call 1-888-825-5249 or visit our website at www.serevent.com.

What are the ingredients in SEREVENT DISKUS?

Active ingredient: salmeterol xinafoate
Inactive ingredient: lactose monohydrate (contains milk proteins)

Instructions for Use

For Oral Inhalation Only

Your SEREVENT DISKUS inhaler

Read this information before you start using your SEREVENT DISKUS inhaler:

• Take SEREVENT DISKUS out of the foil pouch just before you use it for the first time. Safely throw away the pouch. The DISKUS will be in the closed position.
Write the date you opened the foil pouch in the first blank line on the label. See Figure A.

Write the “use by” date in the second blank line on the label. See Figure A. That date is 6 weeks after the date you wrote in the first line.

The counter should read 60. If you have an institutional pack (with “INSTITUTIONAL PACK” on the foil pouch), the counter should read 28.

How to use your SEREVENT DISKUS inhaler

Follow these steps every time you use SEREVENT DISKUS.

Step 1. Open your SEREVENT DISKUS.

- Hold the DISKUS in your left hand and place the thumb of your right hand in the thumb grip. Push the thumb grip away from you as far as it will go until the mouthpiece shows and snaps into place. See Figure B.

Step 2. Slide the lever until you hear it click.

- Hold the DISKUS in a level, flat position with the mouthpiece towards you. Slide the lever away from the mouthpiece as far as it will go until it clicks. See Figure C.

- The number on the counter will count down by 1. The DISKUS is now ready to use.

Follow the instructions below so you will not accidentally waste a dose:

- Do not close the DISKUS.
- Do not tilt the DISKUS.
- Do not move the lever on the DISKUS.

Step 3. Inhale your medicine.

- Before you breathe in your dose from the DISKUS, breathe out (exhale) as long as you can while you hold the DISKUS level and away from your mouth. See Reference ID: 3489259
Figure D. Do not breathe into the mouthpiece.

- Put the mouthpiece to your lips. See Figure E. Breathe in quickly and deeply through the DISKUS. Do not breathe in through your nose.

- Remove the DISKUS from your mouth and hold your breath for about 10 seconds, or for as long as is comfortable for you.

- Breathe out slowly as long as you can. See Figure D.

- The DISKUS delivers your dose of medicine as a very fine powder that you may or may not taste or feel. Do not take an extra dose from the DISKUS even if you do not taste or feel the medicine.

Step 4. Close the DISKUS.

- Place your thumb in the thumb grip and slide it back towards you as far as it will go. See Figure F. Make sure the DISKUS clicks shut and you cannot see the mouthpiece.

- The DISKUS is now ready for you to take your next scheduled dose in about 12 hours. When you are ready to take your next dose, repeat Steps 1 through 4.

When should you get a refill?

The counter on top of the DISKUS shows you how many doses are left. After you have taken 55 doses (23 doses from the institutional pack), the numbers 5 to 0
will show in red. See Figure G. These numbers warn you there are only a few
doses left and are a reminder to get a refill.

Figure G

For correct use of the DISKUS, remember:
• Always use the DISKUS in a level, flat position.
• Make sure the lever firmly clicks into place.
• Hold your breath for about 10 seconds after inhaling. Then breathe out fully.
• Do not take an extra dose, even if you did not taste or feel the powder.
• Do not take the DISKUS apart.
• Do not wash the DISKUS.
• Always keep the DISKUS in a dry place.
• Do not use the DISKUS with a spacer device.

If you have questions about SEREVENT DISKUS or how to use your inhaler, call
GlaxoSmithKline (GSK) at 1-888-825-5249 or visit www.serevent.com.

This Medication Guide and Instructions for Use have been approved by the
U.S. Food and Drug Administration.

SEREVENT and DISKUS are registered trademarks of the GSK group of companies.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BADRUL A CHOWDHURY
04/14/2014