



## Patient Information Sheet

### Salmeterol xinafoate inhalation powder (marketed as Serevent Diskus)

**DRUGS-ABOUT.COM**

This is a summary of the most important information about Serevent. For details, talk to your healthcare professional.

---

**FDA ALERT [11/2005] In some patients with asthma, medicines called “long-acting beta-agonists” (LABA) may increase the chance of death from asthma problems.**

**FDA has asked companies that make products containing long-acting beta-agonists, including Serevent, to give special warnings to healthcare professionals and patients about these possible risks.**

**Because LABAs, such as SEREVENT DISKUS, may increase the chance of asthma death in some people:**

- **It should not be the first medicine prescribed for your asthma.**
- **It should not be the only medicine prescribed for your asthma.**
- **It should always be used with another asthma-controller medicine, and only after another asthma-controller, such as a low-to-medium dose inhaled corticosteroid, has not controlled your asthma.**

*This information reflects FDA’s current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.*

---

#### What Is Serevent?

Serevent is a medicine called a “long-acting beta-agonist” and is a long-acting bronchodilator medicine. Bronchodilator medicines help to relax the muscles around the airways in your lungs. Wheezing happens 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 does NOT relieve sudden breathing problems. Always have a short-acting bronchodilator medicine with you to treat sudden breathing problems.

SEREVENT DISKUS is used for:

#### Asthma

- SEREVENT DISKUS is used long-term, twice-a-day, to control symptoms of asthma and prevent wheezing in adults and children ages 4 and older.

**Because SEREVENT DISKUS can increase the chance of death from asthma, it is not for adults and children with asthma who:**

- are well controlled with other asthma-controller medicines such as low-to-medium doses of inhaled corticosteroids
- need only short-acting bronchodilators once in awhile

#### Exercise-Induced Bronchospasm (EIB)

SEREVENT DISKUS is used for the prevention of wheezing (bronchospasm) caused by exercise in adults and children 4 years of age and older.

#### Chronic Obstructive Pulmonary Disease (COPD)

SEREVENT DISKUS is used long-term, twice-a-day in controlling wheezing (bronchospasms) in adults with COPD.

#### What Are The Risks?

*The following are the major potential risks and side effects of Serevent therapy. However, this list is not complete.*

Serevent may worsen your breathing problems. See FDA Alert.

#### **Other possible side effects with Serevent include:**

- allergic reactions including, rash, hives, and swelling of the face, mouth, and tongue
- increased blood pressure
- fast and irregular heartbeat
- chest pain
- headache
- tremor
- nervousness
- throat irritation

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

#### What Should I Tell My Healthcare Professional?

**Before you start using Serevent, tell your healthcare professional if you:**

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



Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
Druginfo@cder.fda.gov



## Patient Information Sheet

### Salmeterol xinafoate inhalation powder (marketed as Serevent Diskus)

- have liver problems
- are pregnant or planning to become pregnant. It is not known if Serevent may harm your unborn baby.
- are breastfeeding. It is not known if Serevent passes into your milk and if it can harm your baby.

#### Can Other Medicines or Food Affect Serevent?

Serevent and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Serevent works or Serevent may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

#### How Do I Use Serevent?

**Read the step-by-step instructions for “How to Use Serevent” that comes with the medicine.** Do not use Serevent unless your healthcare professional has taught you and you understand everything.

Use Serevent exactly as prescribed. Do not use Serevent more often than prescribed.

- Do not use a spacer device with Serevent Diskus. Do not breathe into the Diskus inhaler.
- Do not change or stop any of your medicines to control or treat your breathing problems. Your healthcare professional will adjust your medicines as needed.
- Make sure you always have a short-acting bronchodilator medicine with you. Use your short-acting bronchodilator if you have breathing problems between doses of Serevent.

Call your healthcare professional right away if:

- your breathing problems worsen while you are taking Serevent
- you need to use your short-acting bronchodilator more often
- your short-acting bronchodilator does not work as well for you at relieving symptoms
- you need to use 4 or more inhalations of your short-acting bronchodilator for 2 or more days in a row
- you use 1 whole canister of your short-acting bronchodilator medicine in less than 8 weeks time

**DRUGS-ABOUT.COM**

