



## Patient Information Sheet

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

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

#### What Is Serevent Diskus?

Serevent Diskus 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 Diskus **does not** relieve sudden breathing problems. Always have a short-acting bronchodilator medicine with you to treat sudden breathing problems.

#### Serevent 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 LABA medicines such as Serevent Diskus may increase the chance of death from asthma problems, it is not for adults and children with asthma who:**
  - are well controlled with other asthma-controller medicines such as a low-to-medium dose of an inhaled corticosteroid
  - only need 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 Diskus therapy. However, this list is not complete.*

#### **Serevent Diskus may worsen your breathing problems.**

Long-acting beta-adrenergic agonists, such as salmeterol, the active ingredient in Serevent Diskus, may increase the chance of death from asthma problems in some people. The package insert (labeling) for Serevent Diskus has been revised to include a Medication Guide (FDA-approved patient information) which contains information about these risks (see <http://www.fda.gov/cder/drug/infopage/LABA/default.htm>).

#### **Other possible side effects with Serevent Diskus 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 Diskus**, tell your healthcare professional 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 passes into your milk and if it can harm your baby.

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

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





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#### How Do I Use Serevent Diskus?

**Read the step-by-step "Instructions for Using Serevent Diskus" that are in the Medication Guide and come packaged with the medicine.** Do not use Serevent unless your healthcare professional has taught you and you understand everything.

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

- Do not use a spacer device with Serevent Diskus. Do not breathe into the Diskus inhaler.
- Do not use other medicines that contain a long-acting beta<sub>2</sub> agonist or LABA for any reason.
- 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 Diskus.

Call your healthcare professional right away if:

- your breathing problems worsen while you are taking Serevent Diskus
- you need to use your short-acting bronchodilator more often than usual
- 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
- your peak flow meter results decrease
- your asthma symptoms do not improve after using Serevent Diskus regularly for 1 week.

