



Patient Information Sheet

Fluticasone propionate and salmeterol xinafoate inhalation powder (marketed as Advair Diskus)

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This is a summary of the most important information about Advair. 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 Advair Diskus, to give special warnings to healthcare professionals and patients about these possible risks.

Because LABAs, such as Advair Diskus, may increase the chance of asthma death in some people:

- Advair Diskus should not be the first medicine you use for asthma.
- Advair Diskus should only be used if an inhaled corticosteroid along with once in a while use of a short-acting bronchodilator medicine does not control 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 Advair?

Advair Diskus contains 2 medicines:

- Fluticasone propionate, an inhaled corticosteroid medicine. Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms.
- Salmeterol inhalation powder, a long-acting beta-agonist (LABA) medicine. LABAs 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.

Advair Diskus does NOT relieve sudden breathing problems. Always have a short-acting bronchodilator medicine with you to treat sudden breathing problems.

Advair Diskus is used for:

Asthma

- Advair Diskus is used long-term, twice-a-day, to control symptoms of asthma in adults and children ages 4 and older.

Advair Diskus is not for adults and children whose asthma is well controlled with:

- an inhaled corticosteroid alone
- an inhaled corticosteroid along with once in a while use of a short-acting bronchodilator

Chronic Obstructive Pulmonary Disease (COPD)

Advair Diskus is used long-term, twice-a-day in controlling breathing problems in adults with COPD with chronic bronchitis.

What Are The Risks?

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

Advair Diskus may worsen your breathing problems. See FDA Alert.

Other possible side effects with Advair Diskus include:

- immune system effect and a higher chance for infections
- lower bone mineral density. This may be a problem for people who already have a higher chance for low bone density (osteoporosis).
- eye problems including glaucoma and cataracts. You should have regular eye exams while using Advair.
- slowed growth in children
- increased blood pressure
- fast and irregular heartbeat
- allergic reactions including, rash, hives, and swelling of the face, mouth, and tongue
- headache
- tremor
- nervousness
- throat irritation

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





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What Should I Tell My Healthcare Professional?

Before you start using Advair Diskus, tell your healthcare professional if you:

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- have liver problems
- have osteoporosis
- have an immune system problem
- are pregnant or planning to become pregnant. It is not known if Advair may harm your unborn baby.
- are breastfeeding. It is not known if Advair passes into your milk and if it can harm your baby.

Can Other Medicines or Food Affect Advair?

Advair Diskus 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 Advair works or Advair may affect how your other medicines work. Especially tell your healthcare professional if you take ritonavir. The anti-HIV medicines Norvir and Kaletra contain ritonavir.

Know the medicines you take. Keep a list of them with you to show your healthcare professional.

How Do I Use Advair?

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

- Use Advair exactly as prescribed. Do not use Advair Diskus more often than prescribed.
- Do not use a spacer device with Advair 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 Advair.

Call your healthcare professional right away if:

- your breathing problems worsen while you are taking Advair Diskus
- 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

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