



Patient Information Sheet

Fluticasone propionate and salmeterol xinafoate inhalation aerosol (marketed as Advair HFA)

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

What Is Advair HFA?

Advair HFA 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.

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

Advair HFA is used for:

Asthma

Advair HFA is used long-term, twice-a-day, to control symptoms of asthma in adolescents and adults 12 years of age and older.

- **Because LABA medicines such as salmeterol (one of the medicines in Advair HFA) may increase the chance of death from asthma problems,** Advair HFA 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

What Are The Risks?

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

Advair HFA may worsen your breathing problems.

Long-acting beta-adrenergic agonists, such as salmeterol, an active ingredient in Advair HFA, may increase the chance of asthma death in some people. The package insert (labeling) for Advair HFA includes 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 Advair HFA include:

- immune system effects and a higher chance of infections
- lower bone mineral density. This may be a problem for people who already have a higher chance of 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.

What Should I Tell My Healthcare Professional? **Before you start using Advair HFA,** 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 HFA may harm your unborn baby.
- are breastfeeding. It is not known if Advair HFA passes into your milk and if it can harm your baby.

Can Other Medicines or Food Affect Advair?

Advair HFA 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

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





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supplements. 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 HFA?

Read the step-by-step “Instructions for Using Advair HFA” that are in the Medication Guide and come packaged with the medicine. Do not use Advair HFA unless your healthcare professional has taught you and you understand everything.

- Use Advair HFA exactly as prescribed. Do not use Advair HFA more often than prescribed.
- Do not use other medicines that contain a long-acting beta₂ 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 Advair HFA.

Call your healthcare professional right away if:

- your breathing problems worsen while you are taking Advair HFA
- 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 Advair HFA regularly for 1 week.

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