

MEDICATION GUIDE

ADVAIR[®] HFA [ad' vair] 45/21 Inhalation Aerosol
(fluticasone propionate 45 mcg and salmeterol 21 mcg)

ADVAIR[®] HFA 115/21 Inhalation Aerosol
(fluticasone propionate 115 mcg and salmeterol 21 mcg)

ADVAIR[®] HFA 230/21 Inhalation Aerosol
(fluticasone propionate 230 mcg and salmeterol 21 mcg)

Read the Medication Guide that comes with ADVAIR HFA Inhalation Aerosol 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 ADVAIR HFA?

ADVAIR HFA can cause serious side effects, including:

- 1. People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines, such as salmeterol (one of the medicines in ADVAIR HFA), have an increased risk of death from asthma problems.** It is not known whether fluticasone propionate, the other medicine in ADVAIR HFA, reduces the risk of death from asthma problems seen with salmeterol.
 - **Call your healthcare provider if breathing problems worsen over time while using ADVAIR HFA.** You may need different treatment.
 - **Get emergency medical care if:**
 - breathing problems worsen quickly and
 - you use your rescue inhaler medicine, but it does not relieve your breathing problems.
- 2. ADVAIR HFA 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 inhaled corticosteroids.**
- 3. When your asthma is well controlled, your healthcare provider may tell you to stop taking ADVAIR HFA.** Your healthcare provider will decide if you can stop ADVAIR HFA without loss of asthma control. Your healthcare provider may prescribe a different long-term asthma control medicine for you, such as an inhaled corticosteroid.
- 4. Children and adolescents who take LABA medicines may have an increased risk of being hospitalized for asthma problems.**

What is ADVAIR HFA?

- ADVAIR HFA combines an inhaled corticosteroid medicine, fluticasone propionate (the same medicine found in FLOVENT[®]), and a LABA medicine, salmeterol (the same medicine found in SEREVENT[®]).
- Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms.
- LABA medicines are used in people with asthma and chronic obstructive pulmonary disease (COPD). LABA medicines help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing and shortness of breath. These symptoms can happen 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 HFA is used to control symptoms of asthma and to prevent symptoms such as wheezing in adults and children aged 12 years and older.
- ADVAIR HFA contains salmeterol (the same medicine found in SEREVENT). LABA medicines, such as salmeterol, increase the risk of death from asthma problems.

ADVAIR HFA 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.

Who should not use ADVAIR HFA?

Do not use ADVAIR HFA:

- to treat sudden, severe symptoms of asthma and
- if you are allergic to any of the ingredients in ADVAIR HFA. See the end of this Medication Guide for a list of ingredients in ADVAIR HFA.

What should I tell my healthcare provider before using ADVAIR HFA?

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**
- **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.
- **are allergic to ADVAIR HFA or any other medicines**
- **are exposed to chickenpox or measles**

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. ADVAIR HFA and certain other medicines may interact with each other. This may cause serious side effects. Especially, tell your healthcare provider if you take ritonavir. The anti-HIV medicines NORVIR[®] (ritonavir capsules) Soft Gelatin, NORVIR (ritonavir oral solution), and KALETRA[®] (lopinavir/ritonavir) Tablets contain ritonavir.

Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist each time you get a new medicine.

How do I use ADVAIR HFA?

See the step-by-step instructions for using ADVAIR HFA at the end of this Medication Guide. Do not use ADVAIR HFA unless your healthcare provider has taught you and you understand everything. Ask your healthcare provider or pharmacist if you have any questions.

- Use ADVAIR HFA exactly as prescribed. **Do not use ADVAIR HFA more often than prescribed.** ADVAIR HFA comes in 3 strengths. Your healthcare provider has prescribed the one that is best for your condition.
- The usual dosage of ADVAIR HFA is 2 inhalations 2 times each day (morning and evening). The 2 doses should be about 12 hours apart. Rinse your mouth with water after using ADVAIR HFA.
- If you miss a dose of ADVAIR HFA, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at one time.
- **While you are using ADVAIR HFA 2 times each day, 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 ADVAIR HFA or other asthma medicines unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- ADVAIR HFA does not relieve sudden symptoms. Always have a rescue inhaler medicine with you to treat sudden symptoms. If you do not have an inhaled, short-acting bronchodilator, call your healthcare provider to have one prescribed for you.
- Call your healthcare provider or get medical care right away if:
 - your breathing problems worsen with ADVAIR HFA

- you need to use your rescue inhaler medicine more often than usual
- your rescue inhaler medicine does not work as well for you at relieving symptoms
- you need to use 4 or more inhalations of your rescue inhaler medicine for 2 or more days in a row
- you use 1 whole canister of your rescue inhaler medicine in 8 weeks' time
- 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 ADVAIR HFA regularly for 1 week

What are the possible side effects with ADVAIR HFA?

ADVAIR HFA can cause serious side effects, including:

- **See “What is the most important information I should know about ADVAIR HFA?”**
- **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 the face, mouth, and tongue
 - breathing problems
- **sudden breathing problems immediately after inhaling your medicine**
- **effects on heart**
 - increased blood pressure
 - a fast and irregular heartbeat
 - chest pain
- **effects on nervous system**
 - tremor
 - nervousness
- **reduced adrenal function (may result in loss of energy)**
- **changes in blood (sugar, potassium, certain types of white blood cells)**
- **weakened immune system 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 HFA.
- **slowed growth in children.** A child's growth should be checked often.

- **throat tightness**
- **pneumonia.** ADVAIR HFA contains the same medicine found in ADVAIR DISKUS[®]. ADVAIR DISKUS is used to treat people with asthma and people with chronic obstructive pulmonary disease (COPD). People with COPD have a higher chance of getting pneumonia. ADVAIR DISKUS may increase the chance of getting pneumonia. ADVAIR HFA has not been studied in people with COPD. Call your healthcare provider if you notice any of the following symptoms:
 - increase in mucus (sputum) production
 - change in mucus color
 - fever
 - chills
 - increased cough
 - increased breathing problems

Common side effects of ADVAIR HFA include:

- upper respiratory tract infection
- headache
- throat irritation
- musculoskeletal pain
- nausea and vomiting

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 ADVAIR HFA. 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 do I store ADVAIR HFA?

- Store at room temperature with the mouthpiece down.
- **Contents Under Pressure:** Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 120°F may cause bursting.
- Do not throw into fire or an incinerator.
- Keep ADVAIR HFA and all medicines out of the reach of children.

General Information about ADVAIR HFA

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use ADVAIR HFA for a condition for which it was not prescribed. Do not give your ADVAIR HFA 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 ADVAIR HFA. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for information about ADVAIR HFA that was written for healthcare professionals. You can also contact the company that makes ADVAIR HFA (toll free) at 1-888-825-5249 or at www.advail.com.

What are the ingredients in ADVAIR HFA?

Active ingredients: fluticasone propionate, salmeterol xinafoate

Inactive ingredient: propellant HFA-134a

How to use your ADVAIR HFA

The parts of your ADVAIR HFA:

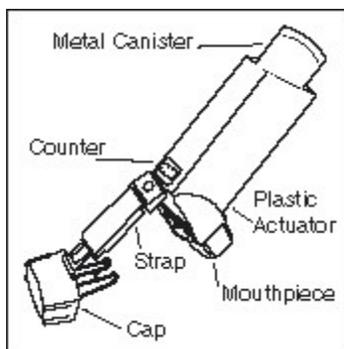


Figure 1

There are 2 main parts to your ADVAIR HFA inhaler—the metal canister that holds the medicine and the purple plastic actuator that sprays the medicine from the canister (see Figure 1).

The inhaler also has a cap that covers the mouthpiece of the actuator. The strap on the cap will stay attached to the actuator.

Do not use the actuator with a canister of medicine from any other inhaler. Do not use an ADVAIR HFA canister with an actuator from any other inhaler.

The canister has a counter to show how many sprays of medicine you have left. The number shows through a window in the back of the actuator.

The counter starts at 124, or at 064 if you have a sample or institutional canister. The number will count down by 1 each time you spray the inhaler. The counter will stop counting at 000.

Never try to change the numbers or take the counter off the metal canister. The counter cannot be reset, and it is permanently attached to the canister.

Before using your ADVAIR HFA:

Take the inhaler out of the foil pouch. Safely throw away the foil pouch and the drying packet that comes inside the pouch. The counter should read 124, or 064 if you have a sample or institutional canister.

The inhaler should be at room temperature before you use it.

Check each time to make sure the canister fits firmly in the plastic actuator. Also look into the mouthpiece to make sure there are no foreign objects there, especially if the strap is no longer attached to the actuator or if the cap is not being used to cover the mouthpiece.

Priming your ADVAIR HFA:

Before you use ADVAIR HFA for the first time, you must prime the inhaler so that you will get the right amount of medicine when you use it. To prime the inhaler, take the cap off the

mouthpiece and shake the inhaler well for 5 seconds. Then spray it 1 time into the air away from your face. Shake and spray the inhaler like this 3 more times to finish priming it. **Avoid spraying in eyes.** The counter should now read 120, or 060 if you have a sample or institutional canister.

You must prime your inhaler again if you have not used it in more than 4 weeks or if you have dropped it. Take the cap off the mouthpiece, shake the inhaler well for 5 seconds, and spray it into the air away from your face. Shake and spray the inhaler like this 1 more time to finish priming it.

Instructions for taking a dose from your ADVAIR HFA:

Read through the 7 steps below before using ADVAIR HFA. If you have any questions, ask your doctor or pharmacist.

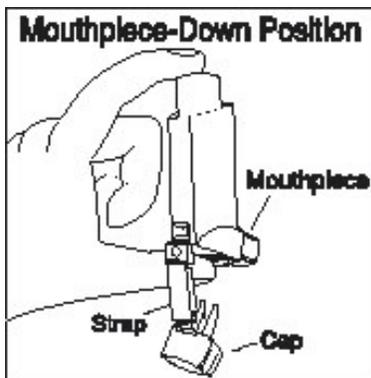


Figure 2

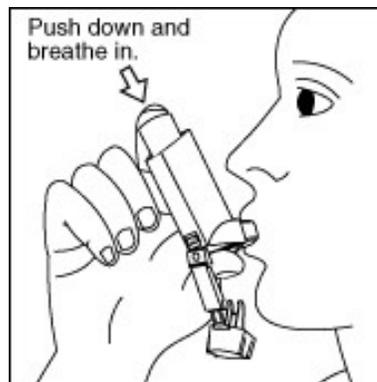


Figure 3

1. Take the cap off the mouthpiece of the actuator. **Shake the inhaler well** for 5 seconds before each spray.
1. Hold the inhaler with the mouthpiece down (see Figure 2). **Breathe out through your mouth** and push as much air from your lungs as you can. Put the mouthpiece in your mouth and close your lips around it.
2. **Push the top of the canister all the way down while you breathe in deeply and slowly through your mouth** (see Figure 3). Right after the spray comes out, take your finger off the canister. After you have breathed in all the way, take the inhaler out of your mouth and close your mouth.
3. **Hold your breath as long as you can**, up to 10 seconds, then breathe normally.
4. Wait about 30 seconds and **shake** the inhaler again for 5 seconds. Repeat steps 2 through 4.
5. After you finish taking this medicine, rinse your mouth with water. Spit out the water. Do not swallow it.
6. Put the cap back on the mouthpiece after every time you use the inhaler, and make sure it snaps firmly into place.

When to replace your ADVAIR HFA:

- **When the counter reads 020**, you should refill your prescription or ask your doctor if you need another prescription for ADVAIR HFA.
- **Throw the inhaler away** when the counter reads 000. You should not keep using the inhaler when the counter reads 000 because you will not receive the right amount of medicine.
- **Do not use the inhaler** after the expiration date, which is on the packaging it comes in.

How to clean your ADVAIR HFA:

Clean the inhaler at least once a week after your evening dose. It is important to keep the canister and plastic actuator clean so the medicine will not build-up and block the spray.

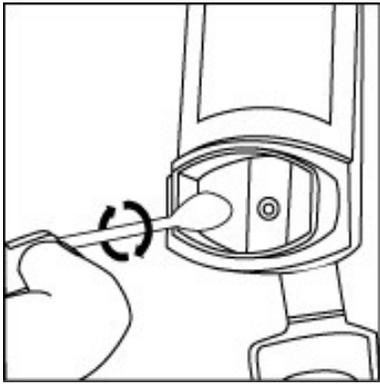


Figure 4

1. Take the cap off the mouthpiece. The strap on the cap will stay attached to the actuator. Do not take the canister out of the plastic actuator.
7. Use a dry cotton swab to clean the small circular opening where the medicine sprays out of the canister. Carefully twist the swab in a circular motion to take off any medicine (see Figure 4).
8. Wipe the inside of the mouthpiece with a clean tissue dampened with water. Let the actuator air-dry overnight.
9. Put the cap back on the mouthpiece after the actuator has dried.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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