

[Complete Prescribing Information and Medication Guide for ADVAIR DISKUS](#)

[Complete Prescribing Information and Medication Guide for ADVAIR HFA](#)

## Important Safety Information About ADVAIR

People with asthma who take long-acting beta<sub>2</sub>-adrenergic agonist (LABA) medicines, such as salmeterol (one of the medicines in ADVAIR), have an increased risk of death from asthma problems (see **Bolded Warning**). [CONTINUED BELOW](#) ▼

**ADVAIR DISKUS<sup>®</sup> 100/50**  
(fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder)

**ADVAIR HFA<sup>®</sup> 115/21**  
(fluticasone propionate 115 mcg and salmeterol 21 mcg)  
Inhalation Aerosol

## Using ADVAIR DISKUS

Take ADVAIR DISKUS out of the box and foil overwrap pouch. Write the "Pouch opened" and "Use by" dates on the label on top of the DISKUS<sup>®</sup>. The "Use by" date is 1 month from the date of opening the pouch.

- The DISKUS will be in the closed position when the pouch is opened
- The **dose indicator** on the top of the DISKUS tells you how many doses are left. The dose indicator number will decrease each time you use the DISKUS. After you have used 55 doses from the DISKUS, the numbers 5 to 0 will appear in red to warn you that there are only a few doses left. If you are using a "sample" DISKUS, the numbers 5 to 0 will appear in red after 23 doses

Taking a dose from the DISKUS requires the following 3 simple steps:

1



### Open.

Hold the DISKUS in one hand and put the thumb of your other hand on the **thumbgrip**. Push your thumb away from you as far as it will go until the mouthpiece appears and snaps into position.

2



### Click.

Hold the DISKUS in a level, flat position with the mouthpiece toward you. Slide the **lever** away from you as far as it will go until it **clicks**. The DISKUS is now ready to use.

Every time the **lever** is pushed back, a dose is ready to be inhaled. This is shown by a decrease in numbers on the dose counter.

3



### Inhale.

Before inhaling your dose, breathe out (exhale) fully while holding the DISKUS level and away from your mouth. **Remember, never breathe out into the DISKUS mouthpiece.**

Put the mouthpiece to your lips. Breathe in quickly and deeply through the DISKUS. Do not breathe in through your nose.

Remove the DISKUS from your mouth. Hold your breath for about

10 seconds, or for as long as comfortable. Breathe out slowly.

The DISKUS delivers your dose of medicine as a very fine powder. Most patients can taste or feel the powder. Do not use another dose from the DISKUS if you do not feel or taste the medicine.

Rinse your mouth with water after breathing in the medicine. Spit the water out. Do not swallow.

4

**CLOSE the DISKUS when you are finished taking a dose so that the DISKUS will be ready for you to take your next dose.** Put your thumb on the thumbgrip and slide the thumbgrip back toward you as far as it will go. The DISKUS will click shut. The lever will automatically return to its original position. The DISKUS is now ready for you to take your next scheduled dose, due in about 12 hours. (Repeat steps 1 to 4.)

**Remember:**

- Never breathe into the DISKUS.
- Never take the DISKUS apart.
- Always ready and use the DISKUS in a level, flat position.
- Do not use the DISKUS with a spacer device.
- After each dose, rinse your mouth with water and spit the water out. Do not swallow.
- Never wash the mouthpiece or any part of the DISKUS. **Keep it dry.**
- Always keep the DISKUS in a dry place.
- Never take an extra dose, even if you did not taste or feel the medicine.
- To avoid releasing or wasting doses once the DISKUS is ready, do not close or tilt the DISKUS, and do not play with the lever or move the lever more than once.
- Discard ADVAIR DISKUS 1 month after you remove it from the foil pouch, or after the dose indicator reads "0," whichever comes first.

For complete instructions, see Medication Guide for ADVAIR DISKUS: [Instructions for Using ADVAIR DISKUS](#).

If you need additional information, live support for using the DISKUS is available at 800-884-0593 (Monday-Friday 8:00am-6:00pm).

ADVAIR DISKUS is for the treatment of asthma in patients 4 years and older.

ADVAIR HFA is for the treatment of asthma in patients 12 years and older.

ADVAIR 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 an inhaled corticosteroid. ADVAIR is not for, and should not be used to treat, sudden, severe symptoms of asthma. ADVAIR won't replace a rescue inhaler.

## Important Safety Information About ADVAIR DISKUS and ADVAIR HFA

- People with asthma who take long-acting beta<sub>2</sub>-adrenergic agonist (LABA) medicines, such as salmeterol (one of the medicines in ADVAIR), have an increased risk of death from asthma problems. It is not known whether fluticasone propionate, the other medicine in ADVAIR, reduces the risk of death from asthma problems seen with salmeterol.
- Call your healthcare provider if breathing problems worsen over time while using ADVAIR. 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.**
- **ADVAIR 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 an inhaled corticosteroid.**
- **When your asthma is well controlled, your healthcare provider may tell you to stop taking ADVAIR. Your healthcare provider will decide if you can stop ADVAIR without loss of asthma control. Your healthcare provider may prescribe a different asthma control medicine for you, such as an inhaled corticosteroid.**
- **Children and adolescents with asthma who take LABA medicines may have an increased risk of hospitalization for asthma problems.**
- Do not use ADVAIR to treat sudden, severe symptoms of asthma. Always have a rescue inhaler medicine with you to treat sudden symptoms.
- Do not use ADVAIR if you are allergic to any of the ingredients in ADVAIR. Do not use ADVAIR DISKUS if you have severe allergy to milk proteins. Ask your doctor if you are not sure. **Do not use ADVAIR more often than prescribed. Do not take ADVAIR with other medicines that contain a LABA for any reason.** Tell your doctor about medicines you take and about all of your medical conditions.
- **ADVAIR can cause serious side effects, including:**
  - **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.** You should avoid exposure to chickenpox and measles, and, if exposed, consult your healthcare provider without delay. Worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex may occur.
  - **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.** A child's growth should be checked often.
  - ADVAIR HFA can cause **throat tightness.**
- **Common side effects of ADVAIR DISKUS for asthma include upper respiratory tract**

infection, throat irritation, hoarseness and voice changes, thrush in the mouth and throat, bronchitis, cough, headache, nausea, and vomiting. In children with asthma, infections in the ear, nose, and throat are common.

- **Common side effects of ADVAIR HFA for asthma include** upper respiratory tract infection, headache, throat irritation, musculoskeletal pain, nausea, and vomiting.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.



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