

Patient's Instructions for Use

ADVAIR DISKUS[®] 100/50, 250/50, 500/50 (fluticasone propionate 100, 250, 500 mcg and salmeterol* 50 mcg inhalation powder)

*As salmeterol xinafoate salt 72.5 mcg, equivalent to salmeterol base 50 mcg

FOR ORAL INHALATION ONLY



This leaflet explains how to use ADVAIR DISKUS. Read this leaflet carefully before you start to use your ADVAIR DISKUS. If you have any questions, ask your doctor or pharmacist.

How to Use Your ADVAIR DISKUS

Follow the instructions below. If you have any questions, ask your doctor or pharmacist.

When you take the ADVAIR DISKUS out of the box and foil overwrap pouch, write the "Pouch opened" and "Use by" dates on the label in the space provided on the device. The "Use by" date is 1 month from date of opening.

The DISKUS[®] inhalation device 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 the DISKUS has delivered 55 doses (23 doses for the institutional or sample pack), numbers 5 to 0 will appear in **red** to warn you that there are only a few doses left (see Figure 1).

Taking a dose of ADVAIR DISKUS requires the following 3 simple steps: Open, Click, Inhale.



Figure 1

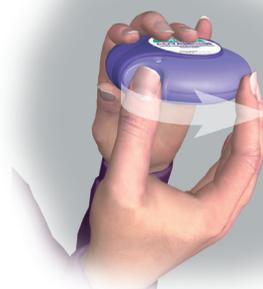


Figure 2

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 (see Figure 2).

2 CLICK: Hold the DISKUS in a level, horizontal position with the mouthpiece towards you. Slide the **lever** away from you as far as it will go until it **clicks** (see Figure 3). 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. **To avoid releasing or wasting doses:**

- Do not close the DISKUS.
- Do not tilt the DISKUS.
- Do not play with the lever.
- Do not advance the lever more than once.

3 INHALE: Before inhaling your dose of ADVAIR DISKUS, breathe out as far as is comfortable, holding the DISKUS level and away from your mouth (see Figure 4). **Remember, never breathe out into the DISKUS mouthpiece.**

Put the mouthpiece to your lips (see Figure 5). Breathe in quickly and deeply through the DISKUS, not through your nose.

Remove the DISKUS from your mouth. Hold your breath for about 10 seconds, or for as long as is comfortable. Breathe out slowly.

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 towards you as far as it will go (see Figure 6). 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 approximately 12 hours. (Repeat steps 1 through 3.)



Figure 5



Figure 6



REMEMBER:

- Never exhale into the DISKUS.
- Never attempt to take the DISKUS apart.
- Always activate and use the DISKUS in a level, horizontal position.
- Do not use the DISKUS with a spacer device.
- After inhalation, rinse the mouth with water without swallowing.
- 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 feel you did not receive a dose.

Storing Your ADVAIR DISKUS

Store at controlled room temperature, 20° to 25°C (68° to 77°F), in a dry place away from direct heat or sunlight. Keep out of reach of children. The DISKUS inhalation device is not reusable. The device should be discarded 1 month after removal from the moisture-protective foil overwrap pouch or after all blisters have been used (when the dose indicator reads "0"), whichever comes first. Do not attempt to take the device apart.

REMEMBER: This medicine has been prescribed for you by your doctor. DO NOT give this medicine to anyone else.

Further Information

This leaflet does not contain the complete information about your medicine. If you have any questions, or are not sure about something, then you should ask your doctor or pharmacist.

You may want to read this leaflet again. Please DO NOT THROW IT AWAY until you have finished your medicine.

Your doctor has determined that this product is likely to help your personal health. **USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR DOCTOR.** If you have any questions about alternatives, consult with your doctor.



Information for the Patient

ADVAIR DISKUS® 100/50

(fluticasone propionate 100 mcg and salmeterol* 50 mcg inhalation powder)

ADVAIR DISKUS® 250/50

(fluticasone propionate 250 mcg and salmeterol* 50 mcg inhalation powder)

ADVAIR DISKUS® 500/50

(fluticasone propionate 500 mcg and salmeterol* 50 mcg inhalation powder)

*As salmeterol xinafoate salt 72.5 mcg, equivalent to salmeterol base 50 mcg

Please read this leaflet carefully before you take ADVAIR DISKUS. It provides a summary of the information available about your medicine. Keep this leaflet for future use. Read it again every time you refill your prescription because there may be new information.

This leaflet does not contain all the information on ADVAIR DISKUS. For further information or advice, ask your doctor or pharmacist.

What Is ADVAIR DISKUS?

Your doctor has prescribed ADVAIR DISKUS 100/50, ADVAIR DISKUS 250/50, or ADVAIR DISKUS 500/50. The medicine is available in 3 different strengths, and your doctor has chosen the one most suitable for you.

Asthma is a long-term condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest tightness, and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscles surrounding the airways) and inflammation (swelling and irritation of the airways).

Chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis is a long-term, progressively worsening condition that restricts airflow into and out of the lungs. The main cause of COPD is exposure to lung irritants, including tobacco smoke and airborne pollutants, which may lead to bronchoconstriction, inflammation, and lung tissue damage.

ADVAIR DISKUS contains 2 medicines, fluticasone propionate (a synthetic corticosteroid) and salmeterol xinafoate (a long-acting bronchodilator), which work in different ways in the lungs to improve lung function and symptoms in patients with asthma. Fluticasone propionate is used to reduce the airway inflammation and salmeterol, a long-acting bronchodilator, helps prevent and relieve bronchospasm, making it easier to breathe.

Fluticasone propionate and salmeterol in ADVAIR DISKUS work together to improve lung function in patients with COPD associated with chronic bronchitis.

Children should use ADVAIR DISKUS under adult supervision, as instructed by the patient's doctor.

Important Points About ADVAIR DISKUS

- Rare but serious asthma episodes and asthma-related deaths occurred in a study with salmeterol, one of the components of ADVAIR DISKUS. The risk may be greater in African Americans. This study was not designed to show whether the use of an inhaled corticosteroid like fluticasone propionate, the other component of ADVAIR DISKUS, protects from these risks. Therefore, it is not known whether the findings of this study apply to ADVAIR DISKUS.**
- TELL YOUR DOCTOR if you are:**
 - pregnant (or intending to become pregnant).
 - breastfeeding a baby.
 - allergic to ADVAIR DISKUS, any other medicines, or food products.
 - taking a medicine containing ritonavir (commonly used to treat HIV infection or AIDS).
 - taking other medicines, especially any other orally inhaled bronchodilator or corticosteroids, over-the-counter medicines, and herbal products.
 - exposed to chickenpox or measles.Tell your doctor about any medical conditions you may have, such as heart disease or high blood pressure.
- Tell your doctor immediately if your condition is getting worse, as indicated by any of the following situations.**
 - Your inhaled, short-acting bronchodilator becomes less effective.
 - You need more inhalations than usual of your inhaled, short-acting bronchodilator.
 - You have asthma and you have a significant decrease in your peak flow measurement as previously defined by your doctor.
- DO NOT USE ADVAIR DISKUS TO RELIEVE SUDDEN SYMPTOMS OF SHORTNESS OF BREATH** (e.g., sudden severe onset or worsening of wheezing, cough, chest tightness). **An inhaled, short-acting bronchodilator such as albuterol should be used to relieve sudden symptoms of shortness of breath.** If you do not have an inhaled, short-acting bronchodilator, contact your doctor to have one prescribed for you. **You should continue to take ADVAIR DISKUS as instructed by your doctor.**
- Do not stop taking ADVAIR DISKUS without first talking with your doctor. Stopping medicines like ADVAIR DISKUS can result in rapid worsening of your symptoms.
- It is important that you inhale each dose as your doctor has advised. The label provided by your pharmacist will usually tell you what dose to take and how often. If it doesn't, or if you are not sure, ask your doctor or pharmacist. **Do not use ADVAIR DISKUS more frequently than 2 times daily, morning and evening, approximately 12 hours apart, at the recommended dose of 1 inhalation each time.**
- ADVAIR DISKUS delivers your dose of medicine as a very fine powder **that most, but not all, patients can taste or feel.** Whether or not you are able to taste or feel your dose of medicine, you should not exceed the recommended dose of 1 inhalation each morning and evening, approximately 12 hours apart. If you are not sure you are receiving your dose of ADVAIR DISKUS, contact your doctor or pharmacist.
- You may breathe more easily after the first dose of ADVAIR DISKUS; however, it may take 1 week or longer to achieve maximum benefit. It is **IMPORTANT THAT YOU USE ADVAIR DISKUS REGULARLY. DO NOT STOP TREATMENT EVEN IF YOU ARE FEELING BETTER** unless told to do so by your doctor.
 - If you miss a dose, just take your next scheduled dose when it is due. **DO NOT DOUBLE** the dose.
 - If you have asthma and your symptoms do not improve after using ADVAIR DISKUS regularly for 2 weeks, tell your doctor.
 - While you are taking ADVAIR DISKUS twice daily, you should not use SEREVENT® DISKUS® (salmeterol xinafoate inhalation powder) or FORADIL® AEROLIZER™ (formoterol fumarate inhalation powder) for any reason, including prevention of exercise-induced asthma or the maintenance treatment of asthma or COPD.**
- Long-term use of inhaled corticosteroids, including fluticasone propionate, a component of ADVAIR DISKUS, may increase the risk of some eye problems (cataracts or glaucoma). Regular eye examinations should be considered.
- If you have COPD, you may be at greater risk of developing bone loss (osteoporosis) and the use of corticosteroids, including ADVAIR DISKUS, may increase your risk. Talk to your doctor about ways to reduce your risk.
- Use other asthma or COPD medicines only as directed by your doctor.

Some Possible Side Effects of ADVAIR DISKUS

Some common side effects that have been reported by patients taking ADVAIR DISKUS include:

- Ear, nose, throat infection or irritation
- Lower respiratory tract infections
- Headache and dizziness
- Upset stomach
- Muscle pain or cramps
- Heart beating faster than normal
- Shakiness or nervousness

If you feel unwell or have any symptoms that you do not understand, you should tell your doctor.

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