MEDICATION GUIDE

ADVAIR DISKUS® [*ad′vair disk′us*] 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)
for oral inhalation

What is the most important information I should know about ADVAIR DISKUS?

ADVAIR DISKUS can cause serious side effects, including:

- **People with asthma who take long-acting beta$_2$-adrenergic agonist (LABA) medicines, such as salmeterol (one of the medicines in ADVAIR DISKUS), have an increased risk of death from asthma problems.** It is not known whether fluticasone propionate, the other medicine in ADVAIR DISKUS, reduces the risk of death from asthma problems seen with LABA medicines.
- **It is not known if LABA medicines such as salmeterol increase the risk of death in people with COPD.**
- **Call your healthcare provider if breathing problems worsen over time while using ADVAIR DISKUS.** You may need different treatment.
- **Get emergency medical care if:**
  - your breathing problems worsen quickly
  - you use your rescue inhaler, but it does not relieve your breathing problems
- ADVAIR DISKUS 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 DISKUS. Your healthcare provider will decide if you can stop ADVAIR DISKUS 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 who take LABA medicines may have an increased risk of being hospitalized for asthma problems.

What is ADVAIR DISKUS?

- ADVAIR DISKUS combines the inhaled corticosteroid (ICS) medicine fluticasone propionate and the LABA medicine salmeterol.
- ICS medicines such as fluticasone propionate help to decrease inflammation in the lungs. Inflammation in the lungs can lead to breathing problems.
- LABA medicines such as salmeterol help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.
- ADVAIR DISKUS is not used to relieve sudden breathing problems.
- It is not known if ADVAIR DISKUS is safe and effective in children younger than 4 years.

- ADVAIR DISKUS is used for asthma and COPD as follows:

  Asthma:
  - ADVAIR DISKUS is a prescription medicine used to control symptoms of asthma and to prevent symptoms such as wheezing in adults and children aged 4 years and older.
  - ADVAIR DISKUS contains salmeterol [the same medicine found in SEREVENT® DISKUS® (salmeterol xinafoate inhalation powder)]. LABA medicines such as salmeterol increase the risk of death from asthma problems.
  - ADVAIR DISKUS 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.

  COPD:

  ADVAIR DISKUS 250/50 is a prescription medicine used to treat COPD. COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both. ADVAIR DISKUS 250/50 is used long term as 1 inhalation 2 times each day to improve symptoms of COPD for better breathing and to reduce the number of flare-ups (the worsening of your COPD symptoms for several days).

Who should not use ADVAIR DISKUS?

Do not use ADVAIR DISKUS if you:

- have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- are allergic to fluticasone propionate, salmeterol, or any of the ingredients in ADVAIR DISKUS. See "What are the ingredients in ADVAIR DISKUS?" below for a complete list of ingredients.

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

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 weak bones (osteoporosis)
- have an immune system problem
- have eye problems such as glaucoma or cataracts
- are allergic to any of the ingredients in ADVAIR DISKUS, any other medicines, or food products. See "What are the ingredients in ADVAIR DISKUS?" below for a complete list of ingredients.
- have any type of viral, bacterial, or fungal infection
- are exposed to chickenpox or measles
- have any other medical conditions
- are pregnant or planning to become pregnant. It is not known if ADVAIR DISKUS may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in ADVAIR DISKUS pass into your milk and if they can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ADVAIR DISKUS and certain other medicines may interact with each other. This may cause serious side effects. Especially, tell your healthcare provider if you take antifungal or anti-HIV medicines.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use ADVAIR DISKUS?

Read the step-by-step instructions for using ADVAIR DISKUS at the end of this Medication Guide.

What should I avoid while using ADVAIR DISKUS?

- **Do not** use ADVAIR DISKUS unless your healthcare provider has taught you how to use the inhaler and you understand how to use it correctly.
- Children should use ADVAIR DISKUS with an adult's help, as instructed by the child's healthcare provider.
- ADVAIR DISKUS comes in 3 different strengths. Your healthcare provider prescribed the strength that is best for you.
- Use ADVAIR DISKUS exactly as your healthcare provider tells you to use it. **Do not** use ADVAIR DISKUS more often than prescribed.
- Use 1 inhalation of ADVAIR DISKUS 2 times each day. Use ADVAIR DISKUS at the same time each day, about 12 hours apart.
- If you miss a dose of ADVAIR DISKUS, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at 1 time.
- If you take too much ADVAIR DISKUS, call your healthcare provider or go to the nearest hospital emergency room right away if you have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness.
- **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 DISKUS 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 DISKUS does not relieve sudden breathing problems.** Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.
- Call your healthcare provider or get medical care right away if:
  - your breathing problems get worse
  - you need to use your rescue inhaler more often than usual
  - your rescue inhaler does not work as well to relieve your symptoms
  - you need to use 4 or more inhalations of your rescue inhaler in 24 hours for 2 or more days in a row
  - you use 1 whole canister of your rescue inhaler in 8 weeks
  - 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 DISKUS regularly for 1 week.

What are the possible side effects of ADVAIR DISKUS?

ADVAIR DISKUS can cause serious side effects, including:

- **See "What is the most important information I should know about ADVAIR DISKUS?"**
- **fungal infection in your mouth or throat (thrush).** Rinse your mouth with water without swallowing after using ADVAIR DISKUS to help reduce your chance of getting thrush.
- **pneumonia.** People with COPD have a higher chance of getting pneumonia. ADVAIR DISKUS may increase the chance of getting pneumonia. Call your healthcare provider if you notice any of the following symptoms:
  - increase in mucus (sputum) production
  - chills

- change in mucus color
- fever
- increased cough
- increased breathing problems

- **weakened immune system and increased chance of getting infections (immunosuppression)**
- **reduced adrenal function (adrenal insufficiency).** Adrenal insufficiency is a condition where the adrenal glands do not make enough steroid hormones. This can happen when you stop taking oral corticosteroid medicines (such as prednisone) and start taking a medicine containing an inhaled steroid (such as ADVAIR DISKUS). During this transition period, when your body is under stress such as from fever, trauma (such as a car accident), infection, surgery, or worse COPD symptoms, adrenal insufficiency can get worse and may cause death.

  Symptoms of adrenal insufficiency include:
  - feeling tired
  - lack of energy
  - weakness
  - nausea and vomiting
  - low blood pressure
- **sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop using ADVAIR DISKUS and call your healthcare provider right away.
- **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 your face, mouth, and tongue
  - breathing problems
- **effects on heart**
  - increased blood pressure
  - a fast or irregular heartbeat
  - chest pain
- **effects on nervous system**
  - tremor
  - nervousness
- **bone thinning or weakness (osteoporosis)**
- **slowed growth in children.** A child's growth should be checked often.
- **eye problems including glaucoma and cataracts.** You should have regular eye exams while using ADVAIR DISKUS.
- **changes in laboratory blood values (sugar, potassium, certain types of white blood cells)**

Common side effects of ADVAIR DISKUS include:

Asthma:
- upper respiratory tract infection
- throat irritation
- hoarseness and voice changes
- thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this.
- bronchitis
- cough
- headache
- nausea and vomiting

In children with asthma, infections in the ear, nose, and throat are common.

COPD:
- thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this.
- viral respiratory infections
- headache

- throat irritation
- hoarseness and voice changes
- muscle and bone pain

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 DISKUS. 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 should I store ADVAIR DISKUS?

- Store ADVAIR DISKUS at room temperature between 68°F and 77°F (20°C and 25°C). Keep in a dry place away from heat and sunlight.
- Store ADVAIR DISKUS in the unopened foil pouch and only open when ready for use.
- Safely throw away ADVAIR DISKUS in the trash 1 month after you open the foil pouch or when the counter reads **0**, whichever comes first.
- **Keep ADVAIR DISKUS and all medicines out of the reach of children.**

General information about the safe and effective use of ADVAIR DISKUS.

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use ADVAIR DISKUS for a condition for which it was not prescribed. Do not give your ADVAIR DISKUS 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 DISKUS. 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 DISKUS that was written for healthcare professionals.

What are the ingredients in ADVAIR DISKUS?

Active ingredients: fluticasone propionate, salmeterol xinafoate

Inactive ingredients: lactose monohydrate (contains milk proteins)

For more information about ADVAIR DISKUS, call 1-888-825-5249 or visit our website at www.advair.com.

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