

PATIENT INFORMATION

AirDuo® Digihaler® (ayr' due oh di'ji haye'' ler)
(fluticasone propionate and salmeterol) inhalation powder 55 mcg/14 mcg

AirDuo® Digihaler® (ayr' due oh di'ji haye'' ler)
(fluticasone propionate and salmeterol) inhalation powder 113 mcg/14 mcg

AirDuo® Digihaler® (ayr' due oh di'ji haye'' ler)
(fluticasone propionate and salmeterol) inhalation powder 232 mcg/14 mcg

for oral inhalation use

What is AirDuo Digihaler?

- AirDuo Digihaler 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.
- AirDuo Digihaler is a prescription medicine used to control symptoms of asthma and to prevent symptoms such as wheezing in people 12 years of age and older.
- AirDuo Digihaler contains a built-in electronic module that records and stores information about inhaler events. AirDuo Digihaler may be used with, and transmits information to, an App through Bluetooth® wireless technology.
- **AirDuo Digihaler does not need to be connected to the app in order for you to take your medicine.** The electronic module does not control or interfere with delivery of the medicine through the inhaler.
- AirDuo Digihaler contains salmeterol. LABA medicines such as salmeterol when used alone increase the risk of hospitalizations and death from asthma problems. AirDuo Digihaler contains an ICS and a LABA. When an ICS and LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.
- AirDuo Digihaler is not for people 12 years of age and older with asthma who are well controlled with an asthma control medicine, such as a low or medium dose of an inhaled corticosteroid medicine. AirDuo Digihaler is for people 12 years of age and older with asthma who need both an ICS and LABA medicine.
- AirDuo Digihaler is not used to relieve sudden breathing problems and will not replace a rescue inhaler.
- It is not known if AirDuo Digihaler is safe and effective in children younger than 12 years of age.

Do not use AirDuo Digihaler:

- to treat sudden, severe symptoms of asthma.
- if you have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- if you are allergic to fluticasone propionate or any of the inactive ingredients in AIRDUO DIGIHALER. See the end of this leaflet for a complete list of ingredients in AirDuo Digihaler.

Tell your healthcare provider about all of your medical 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 milk proteins.
- have any type of viral, bacterial, fungal, or parasitic infection.
- are exposed to chickenpox or measles.
- are pregnant or plan to become pregnant. It is not known if AirDuo Digihaler may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in AirDuo Digihaler pass into your breast 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. AirDuo Digihaler 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.

How should I use AirDuo Digihaler?

Read the step-by-step instructions for using AirDuo Digihaler at the end of this Patient Information leaflet.

- For detailed instructions on how to set up the App go to www.AirDuoDigihaler.com or call Teva Pharmaceuticals at 1-888-603-0788.
- Connection to the App, having your Bluetooth turned on, or being near your smartphone is not required for your AirDuo Digihaler to work and for you to get your medicine.
- The electronic module does not control or interfere with delivery of the medicine through the inhaler.
- **AirDuo Digihaler is for oral inhalation only.**
- Rinse your mouth with water without swallowing after each dose of AirDuo Digihaler.
- AirDuo Digihaler comes in 3 different strengths. Your healthcare provider prescribed the strength that is best for you or your child.
- Use AirDuo Digihaler exactly as your healthcare provider tells you to use it. **Do not** use AirDuo Digihaler more often than prescribed.
- Use 1 inhalation of AirDuo Digihaler 2 times each day. Use AirDuo Digihaler at the same time each day, about 12 hours apart. If you miss a dose of AirDuo Digihaler, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at one time.
- AirDuo Digihaler does not need priming. **Do not** use a spacer or volume holding chamber with AirDuo Digihaler.
- **Do not** open the cap on your AirDuo Digihaler inhaler until you are ready for your dose because this will waste your medicine or may damage your inhaler.
- If you take too much AirDuo Digihaler, 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.** Examples of other medicines that contain a LABA include salmeterol, formoterol fumarate, arformoterol tartrate, and indacaterol. Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.
- **Do not** stop using AirDuo Digihaler unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- **AirDuo Digihaler does not relieve sudden asthma symptoms. You should not take extra doses of AirDuo Digihaler to relieve sudden asthma symptoms.** Always have a rescue inhaler with you to treat sudden asthma 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.
- 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 AirDuo Digihaler regularly for one week.

What are the possible side effects with AirDuo Digihaler?

AirDuo Digihaler can cause serious side effects, including:

- **fungal infection in your mouth and throat (thrush).** Rinse your mouth with water without swallowing after using AirDuo Digihaler to help reduce your chance of getting thrush.
- **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 AirDuo Digihaler). When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, 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 AirDuo Digihaler and call your healthcare provider right away.
- **serious allergic reactions. Stop using AirDuo Digihaler and** call your healthcare provider or get emergency medical help 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.** The growth of a child should be checked often.
- **eye problems including glaucoma and cataracts.** You should have regular eye exams while using AirDuo Digihaler.
- **changes in laboratory blood values (sugar, potassium, certain types of white blood cells).**

Common side effects of AirDuo Digihaler in patients ages 12 years and older include:

- infection of nose and throat
- thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this.
- back pain
- headache
- cough

These are not all the possible side effects of AirDuo Digihaler. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AirDuo Digihaler?

- Store AirDuo Digihaler at room temperature between 59°F and 77°F (15°C and 25°C).
- Store AirDuo Digihaler in a dry place. Avoid exposure to extreme heat, cold, or humidity.
- Store AirDuo Digihaler in the unopened foil pouch and only open when ready for use.

- Do not take your AirDuo Digihaler apart.
- Keep the yellow cap on the inhaler closed during storage.
- Keep your AirDuo Digihaler inhaler dry and clean at all times.
- Throw away AirDuo Digihaler 30 days after opening the foil pouch, when the dose counter displays '0', or after the expiration date on the product, whichever comes first.

Keep AirDuo Digihaler and all medicines out of the reach of children.

General information about the safe and effective use of AirDuo Digihaler.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use AirDuo Digihaler for a condition for which it was not prescribed. Do not give AirDuo Digihaler to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about AirDuo Digihaler that is written for health professionals.

What are the ingredients in AirDuo Digihaler?

Active ingredients: fluticasone propionate, salmeterol xinafoate

Inactive ingredient: lactose monohydrate (may contain milk proteins)

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For more information about AirDuo Digihaler, call 1-888-603-0788 or visit our website at www.AirDuoDigihaler.com.

This Patient Information leaflet has been approved by the U.S. Food and Drug Administration.

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