

PATIENT INFORMATION

ARMONAIR® DIGIHALER™ (ar´ moe nayr di´ji haye´´ ler)
(fluticasone propionate) inhalation powder 55 mcg
ARMONAIR DIGIHALER (ar´ moe nayr di´ji haye´´ ler)
(fluticasone propionate) inhalation powder 113 mcg
ARMONAIR DIGIHALER (ar´ moe nayr di´ji haye´´ ler)
(fluticasone propionate) inhalation powder 232 mcg

What is ARMONAIR DIGIHALER?

ARMONAIR DIGIHALER is a prescription inhaled corticosteroid (ICS) medicine for the long-term treatment of asthma in people aged 12 years and older.

- ICS medicines such as fluticasone propionate help to decrease inflammation in the lungs. Inflammation in the lungs can lead to breathing problems.
- ARMONAIR DIGIHALER is not used to relieve sudden breathing problems.
- It is not known if ARMONAIR DIGIHALER is safe and effective in children younger than 12 years of age.
- ARMONAIR DIGIHALER contains a built-in electronic module that records and stores information about inhaler events. ARMONAIR DIGIHALER may be used with, and transmits information to, an App through Bluetooth® wireless technology.
- **ARMONAIR 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.

Do not use ARMONAIR DIGIHALER:

- to relieve sudden breathing problems.
- if you have a severe allergy to milk proteins or any of the ingredients in ARMONAIR DIGIHALER. See the end of this Patient Information leaflet for a complete list of ingredients in ARMONAIR DIGIHALER.

Before using ARMONAIR DIGIHALER, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems.
- have weak bones (osteoporosis).
- have an immune system problem.
- have eye problems such as glaucoma or cataracts.
- have tuberculosis, a fungal, bacterial, viral or parasitic infection, or herpes simplex.
- are exposed to chickenpox or measles.
- are pregnant or plan to become pregnant. It is not known if ARMONAIR DIGIHALER may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ARMONAIR DIGIHALER passes into your breast milk and 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. ARMONAIR DIGIHALER and certain other medicines may affect each other causing 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 to your healthcare provider and pharmacist when you get a new medicine.

How should I use ARMONAIR DIGIHALER?

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

- For detailed instructions on how to set up the App go to www.ARMONAIRDIGIHALER.com or call Teva at 1-888-603-0788.
- Connection to the App, having your Bluetooth turned on, or being near your smartphone is not required for your ARMONAIR 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.
- **ARMONAIR DIGIHALER is for oral inhalation use only.**
- Rinse your mouth with water without swallowing after each dose of ARMONAIR DIGIHALER.
- Children should use ARMONAIR DIGIHALER with an adult's help, as instructed by the child's healthcare provider.
- ARMONAIR DIGIHALER comes in 3 different strengths. Your healthcare provider prescribed the strength that is right for you.
- Use ARMONAIR DIGIHALER exactly as your healthcare provider tells you to use it. **Do not** use ARMONAIR DIGIHALER more often than prescribed.
- Use ARMONAIR DIGIHALER 2 times a day (about 12 hours apart) at the same time every day.
- ARMONAIR DIGIHALER does not need priming. Do not use a spacer or volume holding chamber with ARMONAIR DIGIHALER.
- **Do not** open the cap on your ARMONAIR DIGIHALER inhaler until you are ready for your dose because this will waste your medicine or may damage your inhaler.
- It may take 1 to 2 weeks or longer after you start ARMONAIR DIGIHALER for your asthma symptoms to get better. You must use ARMONAIR DIGIHALER regularly.
- **Do not** stop using ARMONAIR DIGIHALER, even if you are feeling better, unless your healthcare provider tells you to.
- If you miss a dose of ARMONAIR DIGIHALER, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at 1 time.
- **ARMONAIR DIGIHALER does not relieve sudden symptoms.** 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.

What are the possible side effects with ARMONAIR DIGIHALER?

ARMONAIR DIGIHALER can cause serious side effects, including:

- **Fungal infection in your mouth and throat (thrush).** Rinse your mouth with water without swallowing after using ARMONAIR 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 ARMONAIR 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
- **Serious allergic reactions.** Call your healthcare provider or get emergency medical help if you get any of the following signs or symptoms of a serious allergic reaction:
 - rash
 - hives
 - swelling of your face, mouth, and tongue
 - breathing problems
- **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 ARMONAIR DIGIHALER.
- **Increased wheezing (bronchospasm).** Increased wheezing can happen right away after using ARMONAIR DIGIHALER. If this occurs, stop using ARMONAIR DIGIHALER and call your healthcare provider. Always have a rescue inhaler with you to treat sudden wheezing.

Common side effects of ARMONAIR DIGIHALER include:

- infection or inflammation of nose and throat (nasopharyngitis)
- upper respiratory tract infection
- thrush in your mouth or throat
- headache
- cough

These are not all the possible side effects with ARMONAIR 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 ARMONAIR DIGIHALER?

- Store ARMONAIR DIGIHALER at room temperature between 59°F and 77°F (15°C and 25°C).
- Store ARMONAIR DIGIHALER in a dry place. Avoid exposure to extreme heat, cold, or humidity.
- Store ARMONAIR DIGIHALER in the unopened foil pouch until you are ready to use a dose of ARMONAIR DIGIHALER.
- Do not take the ARMONAIR DIGIHALER inhaler apart.
- Throw away ARMONAIR DIGIHALER when the dose counter displays **0**, 30 days after opening the foil pouch or after the expiration date on the product, whichever comes first.
- **Keep ARMONAIR DIGIHALER and all medicines out of the reach of children.**

General information about the safe and effective use of ARMONAIR DIGIHALER.

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

You can ask your pharmacist or healthcare provider for information about ARMONAIR DIGIHALER that was written for health professionals.

What are the ingredients in ARMONAIR DIGIHALER?

Active ingredient: fluticasone propionate

Inactive ingredients: alpha lactose monohydrate (contains milk proteins)

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For more information, go to www.ARMONAIRDIGIHALER.com or call 1-888-603-0788.

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

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