

MEDICATION GUIDE

ORALAIR® (OR-AL-AIR): (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)

Carefully read this Medication Guide before you or your child start taking ORALAIR and each time you get a refill. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. Talk with your doctor or pharmacist if there is something you do not understand or you want to learn more about ORALAIR.

What is the Most Important Information I Should Know about ORALAIR?

ORALAIR can cause severe allergic reactions that may be life-threatening. Symptoms of allergic reactions to ORALAIR include:

- Trouble breathing
- Throat tightness or swelling
- Trouble swallowing or speaking
- Dizziness or fainting
- Rapid or weak heartbeat
- Severe stomach cramps or pain, vomiting, or diarrhea
- Severe flushing or itching of the skin

If any of these symptoms occur, stop taking ORALAIR and immediately seek medical care.

For home administration of ORALAIR, your doctor should prescribe auto-injectable epinephrine for you to keep at home for treating a severe reaction, should one occur. Your doctor will train and instruct you on the proper use of auto-injectable epinephrine.

What is ORALAIR

ORALAIR is a prescription medicine used for sublingual (under the tongue) immunotherapy prescribed to treat sneezing, runny or itchy nose, nasal congestion or itchy and watery eyes due to allergy to these grass pollens. ORALAIR may be prescribed for persons 5 to 65 years of age whose doctor has confirmed are allergic to any of the grass pollens contained in ORALAIR.

ORALAIR is taken for about four months before the expected start of the grass pollen season and is continued throughout the grass pollen season.

ORALAIR is NOT a medication that gives immediate relief of allergy symptoms.

Who Should Not Take ORALAIR

You or your child should not take ORALAIR if:

- You or your child has severe, unstable, or uncontrolled asthma
- You or your child had a severe allergic reaction in the past that included any of these symptoms:
 - Trouble breathing
 - Dizziness or fainting

- Rapid or weak heartbeat
- You or your child has ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before.
- You or your child has ever been diagnosed with eosinophilic esophagitis.
- You or your child is allergic to any of the inactive ingredients contained in ORALAIR
 - The inactive ingredients contained in ORALAIR are: mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate and lactose monohydrate

What Should I Tell My Doctor Before Taking ORALAIR

Your doctor may decide that ORALAIR is not the best course of therapy if:

- You or your child has asthma, depending on how severe it is.
- You or your child suffers from lung disease such as chronic obstructive pulmonary disease (COPD).
- You or your child suffers from heart disease such as coronary artery disease, an irregular heart rhythm, or you have hypertension that is not well controlled.
- You or your daughter is pregnant, plans to become pregnant during the time you will be taking ORALAIR, or is breast-feeding.
- You or your child is unable or unwilling to administer auto-injectable epinephrine to treat a severe allergic reaction to ORALAIR.
- You or your child is taking certain medicines that enhance the likelihood of a severe reaction, or interfere with the treatment of a severe reaction. These medicines include:
 - beta blockers and alpha-blockers (prescribed for high blood pressure)
 - cardiac glycosides (prescribed for heart failure or problems with heart rhythm)
 - diuretics (prescribed for heart conditions and high blood pressure)
 - ergot alkaloids (prescribed for migraine headache)
 - monoamine oxidase inhibitors or tricyclic antidepressants (prescribed for depression)
 - thyroid hormone (prescribed for low thyroid activity).

You should tell your doctor if you or your child is taking or has recently taken any other medicines, including medicines obtained without a prescription and herbal supplements. Keep a list of them and show it to your doctor and pharmacist each time you get a new supply of ORALAIR. Ask your doctor or pharmacist for advice before taking ORALAIR.

Are there any reasons to stop taking ORALAIR?

Stop ORALAIR and contact your doctor if you or your child:

- has any type of a serious allergic reaction
- develops throat tightness or swelling of the tongue or throat that causes trouble speaking, breathing or swallowing after taking ORALAIR
- has trouble breathing or asthma or another breathing condition that gets worse
- experiences dizziness or fainting
- develops rapid or weak heartbeat
- experiences severe stomach cramps or pain, vomiting, or diarrhea

- develops severe flushing or itching of the skin
- has heartburn, difficulty swallowing, pain with swallowing, or chest pain that does not go away or worsens
- has any mouth surgery procedures (such as tooth removal), develops any mouth infections, ulcers or cuts in the mouth or throat

How should I take ORALAIR?

Take ORALAIR exactly as your doctor tells you.

ORALAIR is a prescription medicine that is placed under the tongue.

- Remove the ORALAIR tablet from the blister just prior to dosing.
- Place the ORALAIR tablet immediately under the tongue until complete dissolution for at least 1 minute before swallowing.
- Do not take ORALAIR with food or beverage. Food and beverage should not be taken for the following 5 minutes.
- Wash hands after handling the tablet.

Take the first tablet of ORALAIR in your doctor's office. After taking the first tablet, you or your child will be observed for at least 30 minutes for symptoms of a serious allergic reaction.

- The first dose for children will be one 100 IR tablet.
- The first dose for adults will be one 300 IR tablet.

If you or your child tolerates the first dose of ORALAIR, you or your child will continue daily ORALAIR therapy at home.

- The first dose at home for children is two 100 IR tablets.
- The first dose at home for adults is one 300 IR tablet.
- After the first dose at home, the dose for children and adults is one 300 IR tablet each day.

Children should be given each dose of ORALAIR by an adult who will watch for any symptoms of a serious allergic reaction.

Take ORALAIR as prescribed by your doctor until the end of the treatment course. If you forget to take ORALAIR, do not take a double dose. Take the next dose at your normal scheduled time the next day. If you don't take ORALAIR for more than one day, contact your health provider before restarting.

What are the possible side effects of ORALAIR?

In children and adults, the most commonly reported side effects were itching of the mouth, lips, tongue or throat. These side effects, by themselves, are not dangerous or life-threatening.

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For additional information on the possible side effects of ORALAIR, talk with your doctor or pharmacist. You may report side effects to the US Food and Drug Administration (FDA) at 1-800-FDA-1088 or www.fda.gov/medwatch.

How should I store ORALAIR?

Keep ORALAIR out of the reach of children.

Throw away any unused ORALAIR after the expiration date which is stated on the carton and blister pack after “EXP.”

Store ORALAIR in a dry place at room temperature, 20°C to 25°C (68°F to 77°F), in the original package.

General information about ORALAIR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ORALAIR for a condition for which it was not prescribed. Do not give ORALAIR to other people, even if they have the same symptoms. It may harm them.

This Medication Guide summarizes the most important information about ORALAIR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ORALAIR that was written for healthcare professionals. For more information go to www.ORALAIR.com or call Greer Laboratories at 1-855-752-5046.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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