

A photograph of three young men running across a lush green field. In the foreground, a large soccer ball is visible. The man on the left is wearing a red polo shirt and jeans, the man in the middle is wearing a yellow t-shirt and white pants, and the man on the right is wearing a light blue polo shirt, jeans, and a straw hat. They are all smiling and appear to be enjoying their time outdoors. The background shows a line of trees under a clear sky.

**Oralair®**

(Sweet Vernal, Orchard, Perennial Rye,  
Timothy, and Kentucky Blue Grass  
Mixed Pollens Allergen Extract)

Tablet For Sublingual Use

## Rediscover the yard with ORALAIR®

### Indication

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 the grass pollens contained in ORALAIR. ORALAIR may be prescribed for persons 10 to 65 years old whose doctor has confirmed are allergic to any of these grass pollens.

### Important Safety Information

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.

Please see additional Important Safety Information on pages 14 and 15.

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.



Whether your doctor has prescribed ORALAIR® for you, or you asked him or her about ORALAIR, this brochure can answer questions you may have about this medicine. ORALAIR is a prescription medicine used to treat symptoms of allergy confirmed to be due to pollens from sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grasses in people 10 to 65 years old.

## Why am I starting ORALAIR® when I don't have any allergy symptoms?

With ORALAIR®, it's all about timing

It's important to know that ORALAIR is a grass allergy treatment that you start about 4 months before the grass allergy season begins. It is not a medication that gives immediate relief of allergy symptoms. That is why you may be taking ORALAIR when you aren't likely having any symptoms of your grass allergy. You will continue to take ORALAIR daily throughout the grass allergy season. The good news is, in medical studies, people who took ORALAIR had less severe symptoms and took less allergy medicine the first grass allergy season than people who did not take ORALAIR.

**You take ORALAIR 4 months before grass allergy season...  
and throughout the grass allergy season**



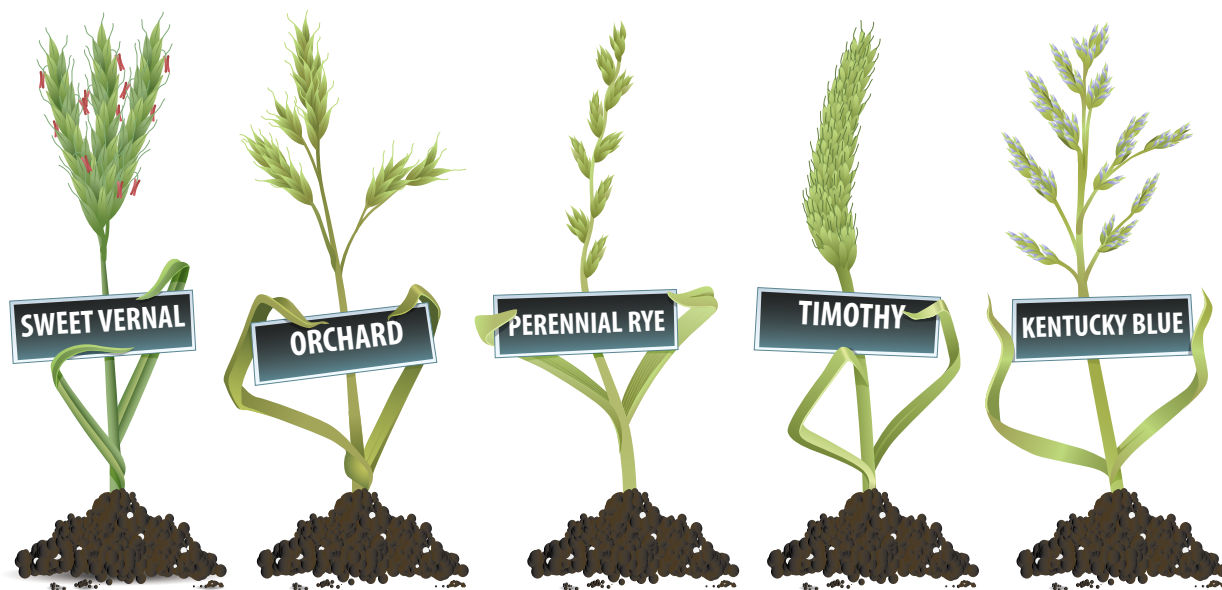
Your doctor will tell you exactly when to start taking ORALAIR and when to stop taking it each year. Always take ORALAIR exactly as your doctor tells you.

**Please see Important Safety Information on pages 14 and 15. Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.**

## What makes ORALAIR® different?

ORALAIR® is a treatment for people who are allergic to 1 or more of 5 different grasses

There are many different types of grasses, and some have pollen that causes bothersome symptoms. ORALAIR is a prescription medicine used for sublingual (under the tongue) immunotherapy prescribed to treat people 10 to 65 years old with sneezing, runny or itchy nose, nasal congestion, or itchy and watery eyes due to allergy to pollens from 5 common grasses. Remember, ORALAIR is not a medication that gives immediate relief of allergy symptoms.



ORALAIR may reduce your allergy symptoms caused by reactions to 1 or more of these 5 grasses.

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These 5 grasses are some of the most common grasses that can trigger allergies. And they can be found just about everywhere in the United States.

If your doctor has prescribed ORALAIR®, or is considering prescribing ORALAIR, it is because he or she has found out that you are allergic to at least 1 of these grasses. And chances are, you may be allergic to more than 1.

**Do not take ORALAIR if you or your child:**

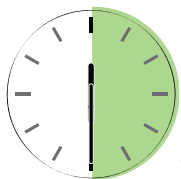
- **Has severe, unstable, or uncontrolled asthma;**
- Had a severe allergic reaction in the past that included trouble breathing, dizziness or fainting, or rapid or weak heartbeat;
- Has ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before;
- Has ever been diagnosed with eosinophilic esophagitis; or
- Is allergic to any of the inactive ingredients contained in ORALAIR.

**Please see additional Important Safety Information on pages 14 and 15. Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.**



# How do I take my first dose of ORALAIR® ?

Your first dose of ORALAIR® is taken in your doctor's office



You or your child will stay at the office for at least 30 minutes after taking the first ORALAIR tablet to be observed for possible side effects, including serious allergic reactions.

In medical studies of 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. Your doctor will be able

to help you tell the difference between severe allergic reactions and other side effects of treatment.

In medical studies, patients who took ORALAIR generally had side effects that were mild to moderate in severity, manageable, and resolved within the first week of treatment. If you have a side effect that bothers you or does not go away, talk with your doctor. He or she may be able to help you manage it.

## ORALAIR safety information

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- 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.**

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## ORALAIR® Starter Packs help you begin treatment

Your doctor will give you a Starter Pack to take home with you. Inside, you will find enough doses of ORALAIR to continue your ORALAIR treatment until your prescription arrives.

If you are 18 years of age or older, all of the ORALAIR tablets inside will be a dose of 300 IR. You will take one 300-IR tablet daily until you receive your first delivery of ORALAIR. If you or your child is 10 to 17 years of age, the Starter Pack will be clearly marked with your Day 2 dose, which consists of two 100-IR ORALAIR tablets. The

rest of the doses will be 300-IR tablets. You will take 1 tablet daily until your prescription arrives from your specialty pharmacy. Your doctor will talk with you more about how to take ORALAIR at home. You can also continue reading to page 8 for more information.



## A specialty pharmacy delivers ORALAIR right to your door

Your doctor and his or her staff will communicate your ORALAIR prescription to the specialty pharmacy. Specialty pharmacies are different because they deliver your prescription right to your door. After beginning your ORALAIR treatment in your doctor's office, you will receive a call from the specialty pharmacy to confirm your

shipping address for each 30-day supply of your ORALAIR prescription. The deliveries will continue for as long as your doctor prescribes.

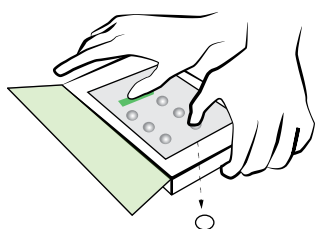
If you prefer to pick up your ORALAIR prescription, your doctor and his or her staff can also send your ORALAIR prescription to a local participating pharmacy.

## How should I take ORALAIR®?

After your first dose taken in your doctor's office, you can take ORALAIR® every day at home

If you have no serious reactions to your first dose of ORALAIR at your doctor's office, you will take it daily at home. By the time grass allergy season begins, you will have already taken an important step toward taking control of your grass allergies. Your doctor will tell you when to stop taking ORALAIR.

### How to take ORALAIR



Remove the ORALAIR tablet from the blister pack right before you take it



Place the ORALAIR tablet under your tongue right away. Keep the tablet there for at least 1 minute, then swallow






Take the ORALAIR tablet without food or drink. Do not eat or drink anything for 5 minutes after you take ORALAIR



Be sure to wash your hands after handling the ORALAIR tablet



At-home dosing for ORALAIR®		
Adults 18-65 years of age	Children & Adolescents 10-17 years of age	
Throughout the grass allergy season <b>1 ORALAIR 300-IR tablet each day</b>	Day 2 <b>2 ORALAIR 100-IR tablets</b>	Day 3 and throughout the grass allergy season <b>1 ORALAIR 300-IR tablet each day</b>
	 (under adult supervision)	

## If you miss a dose

If you forget to take ORALAIR, do not take a double dose and take the next dose at your normal scheduled time the next day. If you don't take ORALAIR for more than 1 day, contact your doctor before restarting.

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.

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## How can ORALAIR® help me?

### Effectiveness of ORALAIR®

ORALAIR can help you reduce your grass allergy symptoms—symptoms like sneezing, runny or itchy nose, nasal congestion or itchy and watery eyes. It can also help you take less allergy medicine during the grass allergy season. Remember, ORALAIR is not a medication that gives immediate relief of allergy symptoms.

#### In medical studies of ORALAIR\*

##### Pre-season



Starting about 4 months before grass allergy season began:

- 1 group took ORALAIR
- 1 group took placebo (sugar pill tablet, with no medicine in it)

##### In season



People continued to take their assigned tablet throughout the grass allergy season and wrote down:

- Their allergy symptoms
- The allergy medicines they took

##### Results



People who took ORALAIR reported that their allergy symptoms were less severe and that they took less allergy medicine than people who did not take ORALAIR.

The effectiveness of ORALAIR was measured in medical studies by a daily combined score of how troublesome their allergy symptoms were and how much other allergy medicine was used. These were measured on a scale of 0 to 3. The symptoms measured were sneezing, runny or itchy nose, nasal congestion, and itchy or watery eyes.

\*ORALAIR is approved for use in children 10 years and older.



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Another medical study showed that people who took ORALAIR® before and during 3 grass allergy seasons had more symptom improvement in each year. Your doctor will tell you when to stop taking ORALAIR.

**Do not take ORALAIR if you or your child:**

- **Has severe, unstable, or uncontrolled asthma;**
- Had a severe allergic reaction in the past that included trouble breathing, dizziness or fainting, or rapid or weak heartbeat;
- Has ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before;

- Has ever been diagnosed with eosinophilic esophagitis; or
- Is allergic to any of the inactive ingredients contained in ORALAIR.

Stop taking ORALAIR and contact your doctor if you or your child has a serious allergic reaction or any reaction that causes trouble speaking, breathing, or swallowing after taking ORALAIR; trouble breathing or a worsening breathing condition; dizziness or fainting; rapid or weak heartbeat; severe stomach cramps, pain, vomiting, or diarrhea; severe skin flushing or itching; heartburn, difficulty or pain with swallowing or chest pain that does not go away; or any mouth procedures, mouth infections, ulcers, or cuts in the mouth or throat.

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# What other support can I get while I'm on ORALAIR®?

The All-Points Allergy™ patient support program is here to help

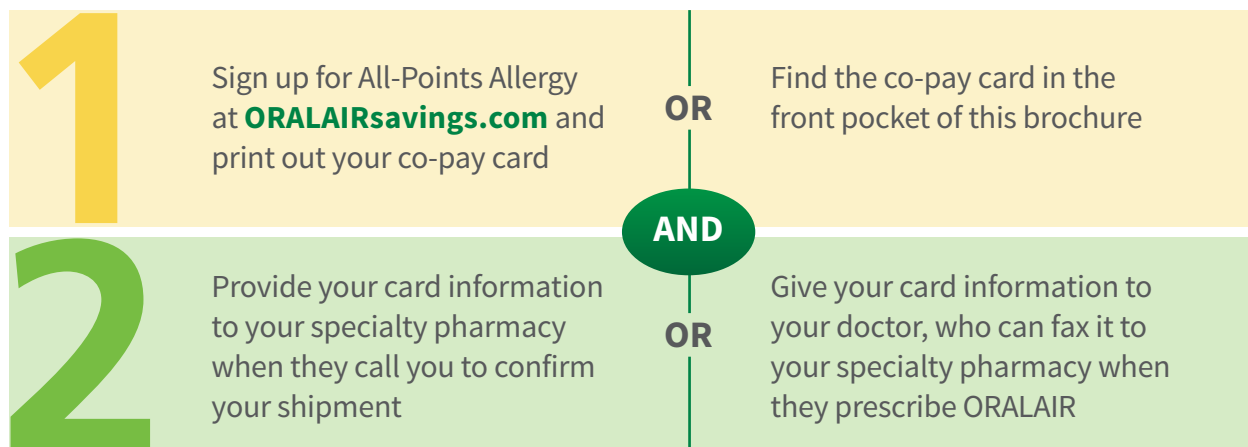
Registering for All-Points Allergy can help you in 3 ways:

- Eligible patients can save money on their ORALAIR® prescription\*
- Receive timely e-mails with helpful information about your ORALAIR treatment
- Get tips on how to prepare for and get through grass allergy season

\*Eligibility restrictions, terms, and conditions apply. Please see [ORALAIRsavings.com](http://ORALAIRsavings.com) or the insert in the front of this brochure for more information.



## How to use your ORALAIR co-pay card



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.

Talk to your doctor before using ORALAIR while pregnant or breastfeeding.

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Be sure to check out all that ORALAIR.com has to offer!

Visit ORALAIR® online to read more about grass allergies and ORALAIR, as well as get helpful tools such as:

- **Grass Pollen Count Tool:** Learn about today's grass pollen count and forecasts for the days to come
- **Allergy Specialist Discussion Guides:** Prepares you on how to talk to your doctor or your child's doctor
- **ORALAIR Treatment Tracker:** Record your progress while taking ORALAIR
- **All-Points Allergy™ patient support program:** Sign up to receive a co-pay card (if eligible) and e-mails about ORALAIR and grass allergies



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- 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.

Do not take ORALAIR if you or your child:

- Has severe, unstable, or uncontrolled asthma;
- Had a severe allergic reaction in the past that included trouble breathing, dizziness or fainting, or rapid or weak heartbeat;
- Has ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before;
- Has ever been diagnosed with eosinophilic esophagitis; or
- Is allergic to any of the inactive ingredients contained in ORALAIR.

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Stop taking ORALAIR® and contact your doctor if you or your child has any mouth surgery procedures (such as tooth removal), develops any mouth infections, ulcers or cuts in the mouth or throat, or has heartburn, difficulty swallowing, pain with swallowing, or chest pain that does not go away or worsens.

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.

You may report side effects to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Talk to your doctor before using ORALAIR while pregnant or breastfeeding.



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