

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using ORALAIR?

ORALAIR contains active ingredients of allergens from a mixture of 5 grass pollens. ORALAIR is used to treat certain grass pollen allergies that are characterised by rhinitis (sneezing, runny or itchy nose, nasal congestion) with or without conjunctivitis (itchy and watery eyes) in adults, adolescents and children above the age of 5 to increase the immunological tolerance towards certain grass pollens, thereby reducing the allergic symptoms.

For more information, see Section [1. Why am I using ORALAIR?](#) in the full CMI.

### 2. What should I know before I use ORALAIR?

Do not use if you have ever had an allergic reaction to any of the ingredients listed at the end of the CMI or if you suffer from severe and/or unstable asthma; your immune system is very weakened; if you suffer from a cancer, if you have any inflammation in your mouth. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use ORALAIR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ORALAIR and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ORALAIR?

Take ORALAIR exactly as your doctor tells you. The therapy is composed of an initiation treatment (including a 3-day dose escalation) and a continuation treatment. After removing the ORALAIR tablet from the blister, place it under your tongue completely disintegrated (at least 2 minutes) before you swallow. More instructions can be found in Section [4. How do I use ORALAIR?](#) in the full CMI.

### 5. What should I know while using ORALAIR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ORALAIR</li><li>• You are advised to take the first tablet under medical supervision and be monitored for 30 minutes. Take these tablets as prescribed until the end of the treatment course.</li><li>• If you experience severe allergic symptoms, stop taking ORALAIR and immediately seek medical care.</li><li>• If your asthma symptoms get noticeably worsen stop the treatment and contact your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take food or beverage at the same time you are taking ORALAIR and for at least 5 minutes afterwards.</li><li>• Do not halve the tablet, it is to be taken whole.</li><li>• If you forget to take ORALAIR, do not take a double dose to make up for forgotten dose.</li><li>• Do not start taking ORALAIR if you are pregnant.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• No effect on the capacity to drive or use machines has been observed with ORALAIR.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 30°C. Store in the original package in order to protect from moisture.</li><li>• Keep out of reach of children.</li></ul>

For more information, see Section [5. What should I know while using ORALAIR?](#) in the full CMI.

### 6. Are there any side effects?

**Very common side effects:** Itching of the mouth, throat irritation and headache.

**Common side effects:** Inflammation in the eyes, itchy or watery eyes; itchy ears; runny or blocked nose, sneezing, sinus pressure; swelling or itching of lips or tongue, tongue pain; oral allergy syndrome, mouth or throat disorders; cough. chest discomfort, heartburn, upset stomach, nausea, vomiting, diarrhoea, persistent skin irritation.

**Serious side effects:** Sudden swelling of the face, mouth, throat or skin; trouble swallowing or breathing; voice changes; low blood pressure, throat tightness; hives and itching of the skin.

For more information, including what to do if you have any side effects, see [Section 6. Are there any side effects?](#) in the full CMI.

# ORALAIR<sup>®</sup> (phonetic pronunciation – O-ral-air)

**Active ingredient(s):** *Mixed 5 Grass Pollens Allergen Extract*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ORALAIR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ORALAIR.**

**Where to find information in this leaflet:**

- [1. Why am I using ORALAIR?](#)
- [2. What should I know before I use ORALAIR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ORALAIR?](#)
- [5. What should I know while using ORALAIR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using ORALAIR?

**ORALAIR contains the active ingredient of allergens from a mixture of 5 grass Pollens of *Dactylis glomerata* (cocksfoot); *Lolium perenne* (rye grass); *Anthoxanthum odoratum* (sweet vernal grass); *Phleum pratense* (timothy) and *Poa pratensis* (meadow grass).**

ORALAIR is used for the treatment of certain grass pollen allergies that are characterised by rhinitis (sneezing, runny or itchy nose, nasal congestion) with or without conjunctivitis (itchy and watery eyes) in adults, adolescents and children above the age of 5.

**ORALAIR is used to increase the immunological tolerance towards grass pollens, thereby building immunity to the specific allergens in grass pollens, thus helping to reduce the allergic symptoms.**

### 2. What should I know before I use ORALAIR?

Before treatment, the allergy is confirmed by a doctor with adequate training and experience in allergic diseases, who will perform the appropriate skin and/or blood tests.

#### Warnings

**Do not use ORALAIR if:**

- You are allergic to any of the other ingredients listed at the end of this leaflet.
- You suffer from severe and/or unstable asthma or experienced severe asthma exacerbation within the last 3 months.
- Your forced expiratory volume in one second (FEV1) is below 70% as assessed by your doctor.
- You have an illness which affects the immune system, you are taking medicines which suppress the immune system or if you have cancer.
- You have mouth ulcers or mouth infections. Your doctor may recommend delaying the start of the

treatment or stopping treatment until your mouth has healed.

Do not start taking ORALAIR if you are pregnant.

**Check with your doctor if :**

- You experience severe allergic symptoms, such as difficulty in swallowing or breathing, changes in your voice, hypotension (low blood pressure) or a feeling of a lump in the throat. Stop the treatment and contact your doctor immediately or go to the Emergency Department at your nearest hospital.
- You have previously had a severe allergic reaction to a drug with allergen extracts.
- Your asthma symptoms get noticeably worse than normal. Stop treatment and contact your doctor immediately.
- You have a cardiovascular disease.
- You are taking a beta blocker (i.e. a class of drugs often prescribed for heart conditions and high blood pressure but also present in some eye drops and ointments), as this drug may decrease the effectiveness of adrenaline, a medicine used to treat serious allergic reactions.
- You are taking MAOIs, tricyclic antidepressants and COMT inhibitors. Allergen immunotherapy in patients treated with mono amine oxidase inhibitors (MAOIs) or tricyclic antidepressants or for Parkinson's disease with COMT inhibitors should be considered carefully as these treatments could potentiate the effect of adrenaline (epinephrine).
- You need mouth surgery or a tooth extraction, you should temporarily stop treatment with ORALAIR until completely healed.
- You experience persistent heartburn or difficulty swallowing. You should contact your doctor.
- You have an autoimmune disease in remission.
- You have any history of allergic inflammation of the oesophagus (eosinophilic oesophagitis). During treatment with ORALAIR, if you have severe or persistent upper abdominal pain, swallowing difficulties or chest pain, please contact your doctor who may reconsider your treatment.

If you take asthma controller and/or reliever medications, do not interrupt your asthma treatment without your doctor's advice as this may worsen the asthma symptoms.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them especially if you have cardiovascular diseases. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Do not start taking ORALAIR if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### **Important information about some of the ingredients of ORALAIR.**

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

#### **Some medicines may interfere with ORALAIR and affect how it works**

If you are taking other allergy medicines such as antihistamines, asthma relief medication or steroids or a medication that blocks a substance called immunoglobulin E (IgE) e.g. omalizumab, discuss with your doctor whether to continue taking them. Do not stop taking these medicines before talking to your doctor. If you stop taking those allergy medicines, you may experience more side effects during ORALAIR treatment.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ORALAIR.**

### **4. How do I use ORALAIR?**

Always take ORALAIR exactly as your doctor has told you. Check with your doctor if you are not sure.

ORALAIR is prescribed by doctors with adequate training and experience in treatment of allergy. With prescriptions for adolescents and children five years and over, the doctor will have the relevant experience in the treatment of patients in this age group.

#### **How much to take / use**

##### Adults, adolescents and children 5 years and over

The treatment is composed of an initiation phase (first month of treatment, including a 3-day dose escalation) and a continuation phase.

##### **Initiation Treatment:**

The treatment with ORALAIR should be initiated as follows:

Day 1	1 tablet of 100 IR
Day 2	2 tablets of 100 IR simultaneously
From day 3	1 tablet of 300 IR

##### **Continuation Treatment:**

The dose is 300 IR (one tablet) each day.

##### **Method of administration**

It is recommended to take the tablets during the day in an empty mouth. Tablets should be placed under the tongue until complete disintegration (at least 2 minutes) and then swallowed. Food or beverage should not be taken for the following 5 minutes. On the first day, one 100 IR tablet should be taken. On the second day of treatment, two 100

IR tablets should be placed under the tongue simultaneously.

There is no experience with ORALAIR in children younger than 5 years and in patients over 65 years of age.

### **How long ORALAIR should be taken for?**

ORALAIR is started 4 months before the pollen season and then continued until the pollen season ends. Each year your doctor will assess if it is suitable for you to restart Oralair treatment. Results from a long-term study have shown that patients treated over 3 consecutive pollen seasons with Oralair, did not require further treatment in the 4<sup>th</sup> year.

### **If you forget to use ORALAIR.**

**Do not take a double dose to make up for a forgotten dose.**

If you interrupted treatment with Oralair for less than one week, you can take up treatment where you have left off.

If you stopped the treatment for more than 7 days, please ask your doctor how you should restart the treatment.

### **If you use too much ORALAIR.**

If you think that you have used too much ORALAIR, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26 in Australia and 0800 POISON (0800 764 766) in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### **5. What should I know while using ORALAIR?**

#### **Things you should do**

##### **Call your doctor straight away if:**

- You have symptoms of an allergic reaction.
- You notice any of the serious side effects listed in CMI occurs, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital
- If you become pregnant, speak to your doctor about whether it is appropriate for you to continue treatment.
- You have to undergo surgery in the mouth or if you are having a tooth pulled, you should stop the treatment with ORALAIR for 7 days to allow your oral cavity to heal. Thereafter, restart the treatment with the previous dosage. If you stopped the treatment for more than 7 days, please ask your doctor how you should restart the treatment.

Remind any doctor, dentist or pharmacist and other health professionals you visit that you are using ORALAIR.

## Things you should not do

- Do not stop using this medicine suddenly. If you stop taking ORALAIR before the full treatment end, you may not have an effect from the treatment.
- Do not take food or beverage at the same time you are taking the medicine and for at least 5 minutes afterwards.
- Do not halve the tablet. Tablet is to be taken whole.
- If you forget to take ORALAIR, do not take a double dose to make up for forgotten dose.

If you have any further questions on the use of this product, ask your doctor.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ORALAIR affects you.**

No effect on the capacity to drive or use machines has been observed with ORALAIR.

## Looking after your medicine

- Keep it in the original pack in order to protect from moisture.
- Keep it below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## When to discard your medicine ORALAIR

Do not use if past the expiry date which is stamped on the carton side panel

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

ORALAIR helps most people with allergies to the selected group of grass pollen, but they may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

**Contact your doctor or nurse immediately if symptoms of an allergic reaction occur.**

During treatment with ORALAIR you will be exposed to substances that may cause application site reactions and/or symptoms, which affect the whole body. You may experience application site reactions (such as itching of the mouth and throat irritation). These reactions usually occur at the beginning of therapy and are temporary, generally diminishing over time.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Stop taking ORALAIR and contact your doctor or hospital immediately if you experience any of the following symptoms:**

- Rapid swelling of face, mouth, throat or skin
- Difficulties in swallowing
- Difficulties in breathing
- Voice changes
- Hypotension (low blood pressure)
- Feeling of fullness in the throat (like a swelling)
- Hives and itching of the skin

Other possible side effects include the following:

### Less serious side effects

Less serious side effects	What to do
<p><b>Mouth, Tongue, &amp; Throat</b></p> <ul style="list-style-type: none"><li>• Itchy mouth</li><li>• Throat irritation</li><li>• Swelling or itching of lips or tongue, tongue pain</li><li>• Mouth disorders: dryness, tingling, numbness, inflammation, pain, blistering, swelling</li><li>• Throat disorders: dryness, discomfort, pain, blistering, swelling</li><li>• Hoarseness</li><li>• Difficulty swallowing</li><li>• Inflammation of the mouth, nose and throat</li><li>• Mouth or tongue ulceration</li><li>• Swollen palate</li><li>• Inflammation of gums, lips, or tongue</li><li>• Salivary gland enlargement</li><li>• Overproduction of saliva</li><li>• Altered taste</li><li>• Belching</li><li>• Throat tightness</li><li>• Throat numbness</li><li>• Foreign body sensation in the throat</li></ul> <p><b>Respiratory System</b></p> <ul style="list-style-type: none"><li>• Asthma</li><li>• Difficulty in breathing</li><li>• Cough</li><li>• Chest discomfort</li><li>• Wheezing</li></ul> <p><b>Eyes &amp; Ears</b></p> <ul style="list-style-type: none"><li>• inflammation in the eyes</li><li>• Itchy or watery eyes</li><li>• Swelling of the eyes</li><li>• Eye redness</li><li>• Dry eye</li><li>• Itchy ears</li><li>• Ear infection</li><li>• Ear discomfort</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>Dizziness (vestibular/ear-related)</li> </ul> <p><b>Nose/Sinus</b></p> <ul style="list-style-type: none"> <li>Rhinitis (stuffy/runny/itchy nose, sneezing, nasal discomfort)</li> <li>Sinus congestion</li> </ul> <p><b>Gastrointestinal System</b></p> <ul style="list-style-type: none"> <li>Heartburn</li> <li>Upset stomach</li> <li>Stomach pain</li> <li>Diarrhoea</li> <li>Vomiting</li> <li>Nausea</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>Persistent skin condition: dryness, redness, itching</li> <li>Hives</li> <li>Itching</li> <li>Rash</li> <li>Acne</li> <li>Cold sores</li> <li>skin lesions from scratching</li> <li>Flushing</li> <li>Swelling of face</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>Headache</li> <li>Depression</li> <li>Tiredness</li> <li>Sleepiness</li> <li>Anxiety</li> </ul> <p><b>Immunological reactions</b></p> <ul style="list-style-type: none"> <li>Allergic reaction with swelling of face and throat</li> <li>Hypersensitivity</li> <li>Increase of eosinophil count (immune system blood cells)</li> <li>Swollen lymph nodes</li> </ul> <p><b>Lymphatic System</b></p> <ul style="list-style-type: none"> <li>Swollen lymph nodes</li> </ul> <p><b>General / Systemic</b></p> <ul style="list-style-type: none"> <li>Flu-like illness</li> </ul>	

#### Additional less serious side effects in children

Less serious side effects in children	What to do
<p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li>Cough</li> <li>Bronchitis</li> <li>Chest pain</li> <li>Worsening of asthma</li> </ul> <p><b>Immunological reactions</b></p> <ul style="list-style-type: none"> <li>Systemic allergic reaction</li> </ul> <p><b>Nose/Mouth/Throat</b></p> <ul style="list-style-type: none"> <li>Nose and throat inflammation</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects in children	What to do
<ul style="list-style-type: none"> <li>Mouth oedema</li> <li>lump feeling in the throat</li> <li>Tonsillitis</li> <li>Oral allergy syndrome</li> <li>Lip inflammation</li> <li>Tongue inflammation</li> </ul> <p><b>Eye/ear</b></p> <ul style="list-style-type: none"> <li>Ear discomfort</li> </ul> <p><b>Gastrointestinal System</b></p> <ul style="list-style-type: none"> <li>Oesophageal inflammation</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or Medsafe (New Zealand) at <https://www.medsafe.govt.nz/safety/report-a-problem.asp>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

ORALAIR is only available with a doctor's prescription.

### What ORALAIR contains

<b>Active ingredient (main ingredient)</b>	Mixed 5 Grass Pollen Allergen Extract: <ul style="list-style-type: none"> <li>Dactylis glomerata (cocksfoot)</li> <li>Lolium perenne (rye grass)</li> <li>Anthoxanthum odoratum (sweet vernal grass)</li> <li>Phleum pratense (timothy)</li> <li>Poa pratensis (meadow grass)</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>Mannitol</li> <li>Microcrystalline cellulose</li> <li>Croscarmellose sodium</li> <li>Colloidal anhydrous silica</li> <li>Magnesium stearate</li> <li>Lactose monohydrate</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ORALAIR looks like

ORALAIR tablets are round, biconvex, white to beige, and slightly speckled. The 100 IR tablet is engraved with 100 on both sides while the 300 IR tablet is engraved with 300 on both sides.

ORALAIR Initiation Treatment sublingual tablets 100 IR and 300 IR contain a small blister with 3 tablets of 100 IR concentration and a large blister with 28 tablets of 300 IR concentration.

or

ORALAIR Initiation Treatment sublingual tablets 100 IR and 300 IR contain a small blister with 3 tablets of 100 IR concentration and a large blister with 7 tablets of 300 IR concentration.

ORALAIR Continuation Treatment sublingual tablets 300 IR contain blisters with 30 tablets of 300 IR concentration. The continuation treatment is available in packs of 30, 90 or 100 tablets.

**Registration numbers:**

In Australia:

ORALAIR Initiation Treatment sublingual tablets 100 IR and 300 IR – (AUST R 167565)

ORALAIR Continuation Treatment sublingual tablets 300 IR - (AUST R 167566)

In New Zealand

ORALAIR Initiation Treatment sublingual tablets 100 IR and 300 IR - TT50-8694

ORALAIR Continuation Treatment sublingual tablets 300 IR - TT50-8694a

**Who distributes ORALAIR**

**AUSTRALIA:**

Stallergenes Australia Pty Ltd  
Suite 2408,  
4 Daydream Street,  
Warriewood,  
New South Wales 2102  
Ph: 1800 824 166

**NEW ZEALAND:**

Stallergenes Greer New Zealand Limited  
Level 1, 24 Manukau Road,  
Epsom, Auckland 1023  
Ph: 0800 824 166

This leaflet was prepared in December 2025.