Package leaflet: Information for the user

ORALAIR 300 IR sublingual tablets

For use in adults, adolescents and children above the age of 5

Grass pollen allergen extract from:
Cocksfoot (*Dactylis glomerata* L.), Sweet vernal grass (*Anthoxanthum odoratum* L.), Rye grass (*Lolium perenne* L.), Meadow grass (*Poa pratensis* L.) and Timothy (*Phleum pratense* L.)

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What ORALAIR is and what it is used for

ORALAIR contains an allergen extract. The treatment with ORALAIR is intended to increase the immunological tolerance towards grass pollens, and thereby reducing the allergic symptoms. ORALAIR is used for the treatment of grass pollen allergy that is characterised by rhinitis (sneezing, runny or itchy nose, nasal congestion) with or without conjunctivitis (itchy and watery eyes) in adults, adolescents and children from the age of 5 years.

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

2. What you need to know before you take ORALAIR

Do not take ORALAIR if:
- You are allergic to any of the other ingredients of this medicine (listed in Section 6);
- You suffer from severe and/or unstable asthma or you experienced severe asthma exacerbation within the last 3 months;

- Your forced expiratory volume in one second (FEV1) is below 80% 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking ORALAIR 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.
- 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 (a class of drugs often prescribed for heart conditions and high blood pressure but also present in some eye drops and ointments).
- You are being treated for depression with tricyclic antidepressants or monoamine oxidase inhibitors (MAOIs), or for Parkinson's disease with catechol-O-methyltransferase (COMT) inhibitors.
- 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.

Talk to your doctor about:

- Any recent disease you may have had,
- Personal or family history of any disease which could affect your immune system,
- If your allergic illness has recently worsened.

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. If you have asthma and a respiratory infection, you should postpone the initiation of the treatment with ORALAIR until your infection has resolved.

You can expect some mild to moderate localised allergic reactions during your treatment. If those reactions are severe, talk to your doctor to see if you need any anti-allergic medicines such as antihistamines.

Use in children and adolescents

ORALAIR is used for the treatment of grass pollen allergic rhinitis with or without conjunctivitis in adolescents and children from the age of 5 years. ORALAIR is not intended for use in children below the age of 5 years.

Other medicines and ORALAIR
Tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines, including medicines without a prescription.

Tell your doctor especially if you are taking certain medicines against depression (tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs)).

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. If you stop taking those allergy medicines you may experience more side effects during ORALAIR treatment. Symptomatic treatment (e.g. antihistamines and/or nasal corticosteroids) may be used with ORALAIR.

Talk to your doctor or pharmacist before taking ORALAIR, if 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 used to treat serious systemic reactions.

ORALAIR with food and drink
Food and drink should not be taken for 5 minutes after taking this medicine

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is no experience for the use of ORALAIR during pregnancy. Therefore, you should not start an immunotherapy if you are pregnant. If you become pregnant while taking this medicine, speak to your doctor about whether it is appropriate for you to continue the treatment.

Breast-feeding

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

You should not start an immunotherapy if you are breast-feeding.
There is no experience for the use of ORALAIR during breast-feeding. No effects on infants who are breast-fed during the treatment are anticipated. If you wish to breast-feed while undergoing treatment, speak to your doctor about whether it is appropriate for you to continue the treatment.

Driving and using machines

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

ORALAIR contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

ORALAIR contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take ORALAIR

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

ORALAIR is prescribed by doctors with adequate training and experience in treatment of allergy. With prescriptions for children, the doctor has the relevant experience in the treatment of children.

You are advised to take the first tablet under medical supervision. This gives you the possibility of discussing possible side effects with your doctor.

Dosage

The treatment is composed of an initiation phase (including a 3-day dose escalation) and a treatment maintenance phase. ORALAIR 300 IR is only intended for the maintenance phase.

Take 1 tablet of 300 IR once a day.

Method of administration

The first dose of ORALAIR should be taken under medical supervision. You should stay under medical observation for at least half an hour after taking the first dose. This is a precaution to monitor your sensitivity to the medicine. It will also give you the chance to discuss possible side effects with your doctor.
Keep the tablet under your tongue until it completely dissolves (at least 1 minute) before you swallow it. It is advisable to take the tablet during the day, in an empty mouth. Do not eat or drink for at least 5 minutes.

Duration of treatment

Take these tablets as prescribed by your doctor until the end of the treatment course. Start treatment about 4 months before the beginning of the pollen season and continue it until the end of the pollen season.

There is no experience with ORALAIR in patients over 65 years of age.

Use in children and adolescents

There is no experience with ORALAIR in children younger than 5 years of age.
There is no experience for more than one pollen season in children.
The dosage in adolescents and children from the age of 5 years is the same as in adults.

If you take more ORALAIR than you should

If you take more ORALAIR than you should, you may experience allergic symptoms including local symptoms from mouth and throat. If you experience severe symptoms, immediately contact your doctor.

If you forget to take ORALAIR

Do not take a double dose to make up for a forgotten dose.
If you have interrupted the 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 stop taking ORALAIR

If you do not complete the treatment course with ORALAIR, you may not have continued benefit from the treatment.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

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

Treatment should only be resumed at the physician’s instructions.

Other possible side effects include the following

Very common (affects more than 1 in 10 people):
- Itchy mouth
- Throat irritation
- Headache

Common (affects less than 1 in 10 people):
– Inflammation in the eyes, itchy or watery eyes
– Itchy ears
– Rhinitis (stuffy nose, runny or itchy nose, sneezing, nasal discomfort), congestion of sinus
– Swelling or itching of lips or tongue, tongue pain
– Mouth disorders (such as dryness, tingling, numbness, inflammation, pain, blistering or swelling)
– Throat disorders (such as dryness, discomfort, pain, blistering or swelling), hoarseness, difficulty in swallowing
– Inflammation of the mouth, nose and throat inflammation
– Asthma, difficulty in breathing
– Cough
– Chest discomfort
– Heartburn, upset stomach, stomach pain, diarrhoea, vomiting, nausea
– Persistent skin condition characterised by dryness, redness and itching, hives, itching

Uncommon (affects less than 1 in 100 people):
– Swelling of the eyes, eye redness, dry eye
– Ear infection, dizziness, ear discomfort
– Mouth or tongue ulceration, swollen palate, inflammation of the gums or lips or tongue
– Salivary gland enlargement, overproduction of saliva
– Altered taste, belching
– Throat tightness, throat numbness, foreign body sensation in the throat
– Wheezing
– Allergic reaction with swelling of the face and throat, hypersensitivity
– Swollen lymph nodes
– Rash, acne, cold sores, skin lesion subsequent to scratching
– Depression, tiredness, sleepiness
– Flu-like illness

Rare (affects less than 1 in 1000 people):
– Swelling face, flushing
– Anxiety
– Increase of eosinophil count

Frequency not known (cannot be estimated from the available data):
Additional oesophageal inflammation has been reported.

The number of side effects reported by adults who were treated with ORALAIR during three consecutive grass pollen seasons in a clinical study decreased over the second and third years.

Side effects in children and adolescents

The following adverse reactions were more frequent in children and adolescents who received ORALAIR than in adults: cough, nose and throat inflammation, mouth oedema (very common), oral allergy syndrome, lip inflammation, lump feeling in the throat, tongue inflammation, ear discomfort (common).
In addition the following adverse reactions were also reported in children and adolescents: bronchitis, tonsillitis (common), chest pain (uncommon).

Additional side effects experience in actual use in adults, adolescents and children (post marketing experience, frequency unknown):
Worsening of asthma, systemic allergic reaction.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ORALAIR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister pack after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ORALAIR contains

- The active substance is a grass pollen allergen extract from: Cocksfoot (*Dactylis glomerata* L.), Sweet vernal grass (*Anthoxanthum odoratum* L.), Rye grass (*Lolium perenne* L.), Meadow grass (*Poa pratensis* L.) and Timothy (*Phleum pratense* L.). One sublingual tablet contains 300 IR.

The IR (Index of Reactivity) expresses the activity and is determined in sensitised patients with a skin test.

- The other ingredients are mannitol (E421); cellulose, microcrystalline; croscarmellose sodium; silica, colloidal anhydrous; magnesium stearate and lactose monohydrate.

What ORALAIR looks like and contents of the pack

The tablets are slightly speckled white to beige, engraved “300” on both surfaces.
One blister with 30 sublingual tablets of 300 IR.
The tablets are supplied in blisters (Alu/Alu) composed of a film (polyamide/aluminium/polyvinyl chloride).
Pack sizes: 30 and 90 sublingual tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Oralair 300 IR Sublingualtabletten
Belgium, Estonia, Germany, Ireland, Italy, Latvia, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia	Oralair 300 IR
Bulgaria, Czech Republic	ORALAIR 300 IR
Croatia	Oralair 300 IR sublingvalne tablete
Denmark, Finland, Norway, Sweden	Aitgrys
France	Oralair 300 IR, comprimé sublingual
Hungary	Oralair 300 IR nyelvalatti tabletta
Lithuania	ORALAIR 300 IR poliežuvines tabletes
Slovenia	Oralair 300 IR podjezične tablete
Spain	ORALAIR 300 IR comprimidos sublinguales

This leaflet was last revised in December 2023.