Package leaflet: Information for the user

ORALAIR 100 IR & 300 IR sublingual tablets
Initiation treatment

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
2. What you need to know before you take ORALAIR
3. How to take ORALAIR
4. Possible side effects
5. How to store ORALAIR
6. Contents of the pack and other information

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);
- if you suffer from severe and/or unstable asthma;
- if your immune system is very weakened or if you suffer from a disease that attacks your immune system;

- if you suffer from a malignant disease (for example cancer);
- if you have any inflammation in your mouth.

Warnings and precautions

Talk to your doctor or pharmacist before taking ORALAIR.

If you have to undergo surgery in the mouth or if you are having a tooth pulled, you should stop the treatment with ORALAIR until your oral cavity completely heals.

Talk to your doctor if you have any history of eosinophilic oesophagitis. During treatment, if you have severe or persistent upper abdominal pain, swallowing difficulties or chest pain, please contact your doctor who may reconsider your treatment.

Other medicines and ORALAIR
Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

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 epinephrine used to treat serious systemic reactions.

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.

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. However, you should not start an immunotherapy if you are breast-feeding. 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.

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.

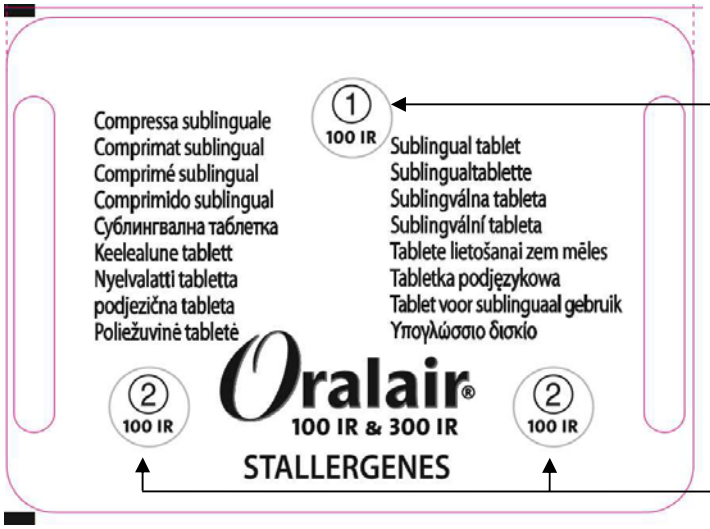
Dosage

The therapy is composed of a treatment initiation phase (including a 3-day dose escalation) and a treatment continuation phase.

This package is to be used for the treatment initiation phase (first treatment month) and contains two blisters:
- One small blister with 3 tablets of 100 IR
- One large blister with 28 tablets of 300 IR

Use the following dosing scheme:

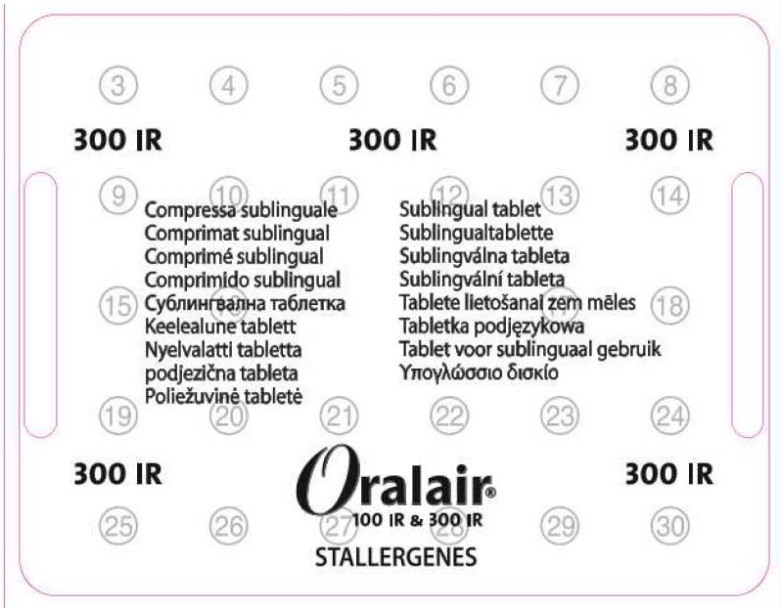
Always start with the small blister:



Day 1: one tablet of 100 IR

Day 2: two tablets of 100 IR

Large blister



Day 1: one tablet of 100 IR

Day 3: one tablet of 300 IR
Day 4: one tablet of 300 IR
Day 5: one tablet of 300 IR
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Day 30: one tablet of 300 IR

From the second month of treatment onwards, continue the therapy with the treatment continuation phase with 300 IR sublingual tablets.

Method of administration

Keep the tablet under your tongue until it completely dissolves (at least 1 minute) before you swallow it. On the second day, put two 100 IR tablets simultaneously under the tongue and then swallow after about 1 minute. It is advisable to take the tablet during the day, in an empty mouth.

Duration of treatment

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 50 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 immediately if you develop or notice:
Severe symptoms affecting the throat or allergic symptoms that affect the whole body (i.e., rapid onset of an illness associated with involvement of the skin and/or mucosa, breathing difficulty, persistent abdominal pain or symptoms related to drop in blood pressure).

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) :
Throat irritation, itchy mouth, headache.

Common (affects less than 1 in 10 people):
Asthma, stomach pain, diarrhoea, vomiting, rhinitis (stuffy nose, runny nose, sneezing, itchy nose, nasal discomfort), inflammation in the eyes, itchy eyes, watery eyes, itchy ears, swelling or itching of lips, swelling or itching or pain of the tongue, mouth disorders (such as dryness, tingling, numbness, inflammation, pain, blistering or swelling), throat disorders (such as dryness, discomfort, pain, blistering or swelling), difficulty in swallowing, hoarseness, cough, chest discomfort, heartburn, upset stomach, nausea, itching, hives, difficulty in breathing, congestion of sinus, persistent skin condition characterised by dryness, redness and itching, skin lesion subsequent to scratching, inflammation of the mouth, nose and throat inflammation.

Uncommon (affects less than 1 in 100 people):
Dry eye, eye redness, swelling of the eyes, ear discomfort, ear infection, inflammation of the gums or lips or tongue, tongue ulceration, swollen palate, salivary gland enlargement, overproduction of saliva, throat numbness, throat tightness, foreign body sensation in the throat, allergic reaction with swelling of the face and throat, belching, swollen lymph nodes, rash, acne, cold sores, flu-like illness, altered taste, sleepiness, dizziness, depression, hypersensitivity, sneezing, tiredness, mouth ulceration.

Rare (affects less than 1 in 1000 people)
Flushing, facial swelling, increase of eosinophil count, anxiety.

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 freeze.

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 100 IR or 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

Sublingual tablet
1 x 3 sublingual tablets of 100 IR in a small blister + 1 x 28 sublingual tablets of 300 IR in a blister

The tablets of 100 IR are slightly speckled white to beige, engraved "100" on both surfaces.

The tablets of 300 IR are slightly speckled white to beige, engraved “300” on both surfaces.

The tablets are supplied in blisters (Alu/Alu) composed of a film (polyamide/aluminium/polyvinyl chloride).

Marketing Authorisation Holder and Manufacturer

STALLERGENES
6 rue Alexis de Tocqueville
92160 ANTONY
France
Tel. 0033 (0) 1 55 59 20 00
Fax 0033 (0) 1 55 59 21 68

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

Austria	ORALAIR 100 IR + 300 IR Sublingualtabletten
Belgium, Bulgaria, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Luxembourg, Netherlands, Poland, Romania, Slovakia	ORALAIR 100 IR & 300 IR
Czech Republic	ORALAIR
Lithuania	ORALAIR 100 IR / 300 IR poliežuvines tabletes
Slovenia	ORALAIR 100 IR in 300 IR podjezične tablete
Spain	ORALAIR INICIO 100 IR & 300 IR

This leaflet was last revised in January 2020.