PACKAGE LEAFLET

Package leaflet: Information for the patient

ACTAIR 100 IR & 300 IR sublingual tablets
For use in adolescents and adults (12-65 years of age)
Standardised House Dust Mite Allergen Extracts
(*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 ACTAIR is and what it is used for

ACTAIR contains allergen extracts from house dust mites.

ACTAIR is used to treat allergic rhinitis (inflammation of the lining of the nose) in adolescents (12-17 years of age) and adults. ACTAIR works by increasing the immunological tolerance to (your body's ability to cope with) house dust mites. The treatment may need to be taken for 3 months before you notice any improvement.

ACTAIR 100 IR is intended only for the dose escalation period and not for maintenance.

Before starting the treatment, your allergy will be diagnosed by a doctor who will perform the appropriate skin and/or blood tests.

The first dose of ACTAIR 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.

ACTAIR is prescribed by doctors with experience in treating allergies.

2. What you need to know before you take ACTAIR

Do not take ACTAIR if:
- You are allergic to any of the excipients (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 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 ACTAIR if you are pregnant.

Warnings and precautions
Talk to your doctor or pharmacist before taking ACTAIR 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 mono amine 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 ACTAIR 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.

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.

Children and adolescents
ACTAIR is used to treat allergic rhinitis in adolescents (12-17 years). ACTAIR is not intended for use in children below 12 years of age.

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

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, 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 ACTAIR during pregnancy. Therefore, treatment with ACTAIR should not be started during pregnancy. If you become pregnant during treatment, speak to your doctor about whether it is appropriate for you to continue the treatment.

There is no experience for the use of ACTAIR during breast-feeding. However, no effects on the breast-fed infants are anticipated. Speak to your doctor whether you may continue to take ACTAIR while breast-feeding your infant.

Driving and using machines
No effect on the capacity to drive or use machines has been observed with ACTAIR.

ACTAIR 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 ACTAIR

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

You are advised to take the first tablet under medical supervision. Your doctor will advise you for how long you should take ACTAIR.

The treatment includes an initiation phase (the dose is progressively increased during a 3-day period) and a maintenance phase.

Initiation treatment
The treatment with ACTAIR should be initiated as follows:

Day 1	1 tablet of 100 IR
Day 2	2 tablets of 100 IR at the same time
From Day 3	1 tablet of 300 IR

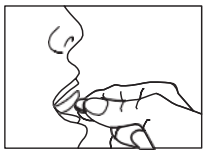
The IR (Index of Reactivity) expresses the activity.
ACTAIR 100 IR is intended only for the dose escalation period and not for maintenance.

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

Use in adolescents
The dosage in adolescents is the same as in adults.

Take ACTAIR as follows:

1. Remove one tablet (or 2 tablets on day 2) from the packaging by pushing the tablet through the foil.
2. Take the tablet during the day, in an empty mouth.
3. Place and keep the tablet under the tongue until it is dissolved, then swallow what is left.



4. Do not eat or drink for at least 5 minutes.
5. Wash your hands after handling the tablet.

If you take more ACTAIR than you should
If you take more ACTAIR than you should, you may experience allergic symptoms including localised symptoms in the mouth and throat. If you get severe symptoms, contact a doctor or a hospital immediately.

If you forget to take ACTAIR
If you have forgotten to take a dose, take it later in the day. Do not take a double dose on any one day to make up for a forgotten dose. If you have not taken ACTAIR for more than 7 days you should contact your doctor before taking ACTAIR again.

If you stop taking ACTAIR
If you do not take this medicine as prescribed then you may not get the beneficial effects of the treatment. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

The side effects may be an allergic response to the allergen you are being treated with. Most allergic side effects last from minutes to hours after taking the medicine, and most will subside when you have been on the treatment for 1 to 3 months.
Stop taking ACTAIR 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

Possible other side effects:
Very common (may affect more than 1 in 10 people):

– Swelling or itching of the mouth
– Throat irritation
– Itchy ear

Common (may affect up to 1 in 10 people):
- Itchy eyes
- Swelling or itching of lips or tongue
- Burning or tingling mouth, inflamed and sore mouth, mouth ulcer
- Altered taste
- Discomfort or pain in the mouth and/or throat
- Throat swelling, swallowing difficulty
- Cough
- Difficulty breathing
- Chest pain
- Stomach pain, indigestion, nausea, diarrhoea
- Itchiness

Uncommon (may affect up to 1 in 100 people):
- Eye redness and inflammation, eye swelling, tearing
- Ear pain or tingling
- Vertigo, dizziness
- Headache
- Malaise or fatigue
- Rhinitis (sneezing, runny or itchy nose, blocked nose)
- Nose bleeds
- Common cold
- Inflammation of lips or tongue
- Oral disorder such as burning mouth, mouth numbness, oral thrush, salivary problems
- Swelling of the palate
- Face swelling
- Dry mouth or throat, thirst
- Mouth and/or throat blisters, mouth and throat swelling due to fruits or vegetables
- Throat disorder such as burning/tingling or tightness in throat, hoarseness, feeling of a lump in the throat, discomfort or swelling in the back of the throat
- Asthma, shortness of breath, wheezing
- Chest discomfort
- Pain in the oesophagus, inflammation of oesophagus or stomach, heartburn
- Vomiting
- Gastroenteritis
- Localised swelling, swelling beneath the skin
- Rash, skin irritation, hives
- Anxiety
- Tingling or prickling sensation
- Abnormal blood results

Rare (may affect up to 1 in 1,000 people):
- Eyelid inflammation, abnormal eyelid contraction, eye irritation
- Blocked ear, ringing in the ears
- Nose discomfort, blocked sinuses
- Gum inflammation, bleeding in the mouth
- Breath odour, burping
- Painful swallowing
- Voice box irritation
- Rapid breathing
- Throat numbness
- Seasonal allergy
- Bronchitis
- Breast pain
- Palpitations, rapid heartbeat
- Oesophagus swelling
- Frequent bowel movements, irritable bowel, having gas
- Irritability, disturbance in attention, numbness, somnolence, speech disorder, tremor
- Blisters, redness of the skin, acute skin reaction, scratching lesions
- Muscle discomfort or contractions
- Urgent urination

If any side effects are causing you concern, you should contact your doctor who will decide whether you need any medicines such as antihistamines to help relieve them.

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 the national reporting system, see below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple app Store

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store ACTAIR

This medicinal product does not require any special storage conditions.

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 after EXP. The expiry date refers to the last day of that month.

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 ACTAIR contains

The active substance is a standardised allergen extract from the house dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*. One sublingual tablet contains 100 IR or 300 IR.
The IR (Index of Reactivity) expresses the activity.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, magnesium stearate, mannitol (E 421) and microcrystalline cellulose.

What ACTAIR looks like and contents of the pack

Sublingual tablet.
The tablets of 100 IR are white to beige, round and biconvex, brown speckled with "SAC" engraved on one side and "100" on the other.

The tablets of 300 IR are white to beige, round and biconvex, brown speckled with "SAC" engraved on one side and "300" on the other.

The tablets are supplied in aluminium blisters with removable aluminium foil in an outer carton.

Pack size: pack of 3 sublingual tablets of 100 IR and 28 sublingual tablets of 300 IR

Marketing Authorisation Holder and Manufacturer

STALLERGENES
6 rue Alexis de Tocqueville
92160 ANTONY
France

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria Actair 100 IR + 300 IR Sublingualtabletten
Belgium Orylmyte 100 IR & 300 IR comprimés sublinguaux
Bulgaria АКТАИР 100 IR и 300 IR сублингвални таблетки
Croatia Orylmyte 100 IR i 300 IR sublingvalne tablete
Czech Republic, Poland, Portugal, Romania ACTAIR
Denmark, Norway, Sweden Aitmyte
France Orylmyte 100 IR, comprimé sublingual
Orylmyte 300 IR, comprimé sublingual
Germany ORYLMYTE 100 IR & 300 IR
Ireland, United Kingdom (Northern Ireland) ACTAIR 100 IR & 300 IR sublingual tablets
Italy, Luxembourg ORYLMYTE
Netherlands Actair 100 IR en 300 IR, tabletten voor sublinguaal gebruik
Slovenia Actair 100 IR in 300 IR podjezične tablete
Slovakia ACTAIR 100 IR sublingválne tablety, ACTAIR 300 IR sublingválne tablety
Spain Actair 100 IR & 300 IR comprimidos sublinguales

This leaflet was last revised in January 2023.