


Actair®

▼ 100 IR and/or 300 IR,
sublingual tablet.

Standardised house dust mite allergen
extracts from *Dermatophagoides*
pteronysinus and *Dermatophagoides*
farinae in equal parts.

PATIENT
INFORMATION
LEAFLET

Only for patients who have been prescribed Actair®.

STALLERGENES  GREER
Life beyond allergy

CONTENTS

What is an allergy?	4
Where do allergies come from?	5
What does house dust mite allergy mean?	6
What are house dust mites?	8
What is allergen immunotherapy?	10
How does sublingual immunotherapy work?	11
What is Actair®?	12
Notes on Actair® therapy	12
Practical tips for house dust mite allergy sufferers	17

There is a leaflet about Actair® inside each pack. Please read it carefully before you start taking this medicine because it contains important information for you. If you have any further questions, ask your doctor or pharmacist.

WHAT IS AN ALLERGY?

An allergy is an exaggerated defence reaction of the human immune system against environmental substances that are harmless in themselves, i.e. the body fights them even though they pose no risk to health.

Allergenic substances, so-called **allergens**, include, for example, house dust mites, tree and grass pollen, moulds/mildew and animal dander/fur.

An allergy develops in several steps:

- The immune system first classifies the allergen as a foreign body. In the process, it produces certain antibodies – a natural defensive measure.
- If the immune system reacts hypersensitively, subsequent contact with the allergen causes an allergic reaction.

WHERE DO ALLERGIES COME FROM?

Scientists are discussing multiple causes for house dust mite allergies and allergies in general:

- On the one hand, a **hereditary risk or genetic predisposition** has been proven. The risk of allergies increases if one or both parents have allergies.
- On the other hand, **individual living conditions** may influence the development of an allergy. Scientific studies indicate that factors such as air pollution, diet and excessive hygiene during a child's early years can promote the development of allergies.

WHAT DOES HOUSE DUST MITE ALLERGY MEAN?

In the case of a house dust mite allergy, **typical symptoms** occur as a result of the immune system's defensive reaction, such as:



Blocked nose



Sneezing



Runny nose



Conjunctivitis, that includes watering, redness and burning of the eyes

These are year-round symptoms.



WHAT ARE HOUSE DUST MITES?

There can be up to 10,000 mites in 1 gram of house dust. The presence of these creatures is not an indication of poor hygiene: **mites are part of our natural environment**. These arachnids, which are invisible to the naked eye, are actually harmless but they leave behind about 200 times their own weight in faeces!

Both the mites' faeces and their bodies can trigger a house dust mite allergy. Mite allergens combine with other dust particles which are stirred up by draughts and movements and then inhaled.

Where do mites occur?

Mites live and reproduce in warm and humid environments. They mainly feed on skin scales. They feel at home in domestic environments, e.g. in beds, upholstered furniture, carpets, bed linen, cuddly toys etc., but also in cars, schools and public transport, for example.

The mites most commonly found in our households are *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*. They belong to the family of house dust mites.



WHAT IS ALLERGEN IMMUNOTHERAPY?

There are different ways of treating an existing allergy:

- Avoidance of the allergen itself
- Treatment of the symptoms
- **Treatment of the root cause : allergen immunotherapy**

Allergen immunotherapy, sometimes called desensitisation, is a **treatment option that addresses the cause of the disease.**

With allergen immunotherapy, the body learns that the allergen does not pose a risk and that the immune system therefore does not need to fight it.

The immune system needs some time to become accustomed to the allergen. It is therefore important for the treatment to be administered on a regular basis over a long period of time. It is generally recommended for the treatment to continue at least **3 years in order to obtain sustained benefits over the long term.** Your doctor will advise you about how long to use Actair®.

HOW DOES SUBLINGUAL IMMUNOTHERAPY WORK?

With sublingual allergen immunotherapy treatments (like Actair®), the allergen is administered in **tablet form under the tongue.**

It is absorbed through the oral mucosa, located in the mouth. You can take this therapy at home by yourself. The first tablet of Actair® should be taken under medical supervision and the patient monitored for at least 30 minutes.



WHAT IS ACTAIR®?

Actair® is a sublingual house dust mite tablet and is used to treat allergic rhinitis (inflammation of the lining of the nose) in adults and adolescents (12-17 years).

The tablet contains standardised house dust mite allergen extracts (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) in freeze-dried form.

Actair® gradually accustoms your body to the allergen, giving you a higher tolerance to house dust mites. The aim here is to **treat the root cause of your allergy and relieve your symptoms**.

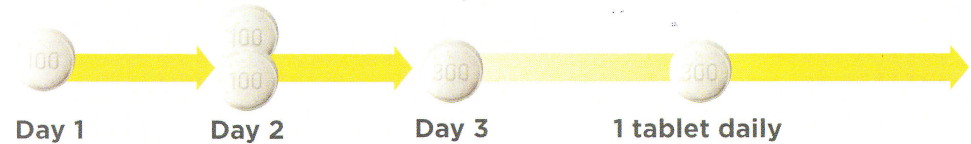
Actair® may need to be taken for 3 months before you notice any improvement.

NOTES ON ACTAIR® THERAPY



Starting allergen immunotherapy with Actair®

In order for you to slowly become accustomed to the allergen, treatment starts with a low allergen dose, gradually increasing over 3 days to reach the maintenance dose.



Always take this medicine exactly as your doctor has told you. Your doctor will advise you for how long you should take Actair®.

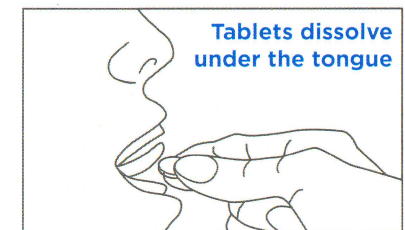


Administration of Actair®

Place the Actair® tablet(s) under your tongue until it is dissolved before swallowing. Food and beverage should not be taken for the following 5 minutes.

You will take the first low-dose tablet of 100 IR* under medical supervision: a 30-minute observation period will allow to monitor your sensitivity to the medicine and to discuss any potential side effects with your doctor.

You can then continue the treatment autonomously: on Day 2 take 2 low-dose tablets of 100 IR simultaneously, and for the subsequent days take 1 regular-dose tablet of 300 IR daily.



*IR stands for 'index of reactivity' and refers to the concentration of the allergen per tablet.



Notes on side effect

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.

If you experience any of the following symptoms, stop taking Actair® and contact your doctor or hospital immediately:

- 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

There is more information about side effects in the leaflet in the pack which you should read carefully. If any side effects cause you concern, contact your doctor who will decide whether you need any medicines such as antihistamines to help relieve them.

▼ 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 of the leaflet in the pack for how to report side effects.



Forgotten to take a tablet or interrupted your therapy?

If you forget to take one or more doses for up to 7 days, you can continue treatment the following day with the normal dose (1 Actair® 300 IR tablet). Under no circumstances should you take the forgotten tablets as well. If you interrupt your treatment for a longer period of time, please discuss the continuation of your treatment with your doctor.



When may you not take Actair®?

You should not undergo allergen immunotherapy with Actair® if:

- You are allergic to any of the other ingredients of this medicine: colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, magnesium stearate, mannitol (E421) and microcrystalline cellulose;
- 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 less than 80 %;
- You have a disease that affects your immune system;
- You are taking medicines that suppress the immune system;
- You have cancer;
- You have sores or infections in your mouth.

You should also not start the therapy if you are pregnant.

Please consult your doctor if:

- You have recently taken other medicines
- You are planning to take other medicines

The leaflet in the pack gives more information about when to talk to your doctor or pharmacist if you have other conditions.



PRACTICAL TIPS FOR HOUSE DUST MITE ALLERGY SUFFERERS

You only have symptoms if house dust mite allergens you are allergic to come into contact with your skin. There are some things you can do to reduce the occurrence of mites and limit your contact with them, thus alleviating your symptoms. The main objective is to deprive the house dust mites of food and make their life uncomfortable:



Avoid curtains and carpets

House dust, which plays host to the mites, is particularly prevalent in curtains, carpets and plants, but also in open bookshelves. You should therefore avoid them as much as possible, especially in the bedroom.



Use mite-proof bed covers

Another measure is to use special “encasing” protective covers for pillows, duvets and mattresses, which are pulled under the normal bed linen. These are very tightly woven, air-permeable, breathable covers which encase the bedding all around to make it impermeable to mites. Wash the anti-allergy covers and also the blankets and pillows at least every 3 months at 60°C.



Thoroughly ventilate your room and bedding

Since house dust mites feel particularly comfortable in a warm and humid climate, you should air all of your rooms, especially the bedroom, several times a day using the cross or stack ventilation methods. Try to keep the temperature in the bedroom at a maximum of 18°C.



Change bed linen weekly

Change your bed linen once a week and wash it at 60°C. This will eliminate the the mites' food source – hair and skin scales –, mites' faeces and the mites themselves which are the cause of the symptoms.



Do not comb your hair or change your clothes in the bedroom

It is advisable not to comb your hair or change your clothes in your bedroom, because this loosens many skin flakes and hairs that serve as the house dust mites' food source.



Keep pets out of the bedroom or avoid keeping pets at all

Pet dander and fur provide additional food for mites. In addition, pets stir up dust as they move and increase the air humidity.



Wash or freeze cuddly toys

You should regularly wash stuffed animals or cuddle cushions at 60°C. If this is not possible, you can also freeze them at -18°C for 12 hours to kill the mites and then wash them at a low temperature or vacuum them to remove the dead mites.



Use anti-allergy vacuum cleaner

When vacuuming, use a HEPA (High Efficiency Particulate Air) filter system if possible. Vacuum carpets, rugs, upholstered furniture and mattresses with a rotating brush attachment.



Wipe surfaces using a damp cloth

Dust and dirt on smooth surfaces are best removed using a damp cloth. Where possible, you should damp mop floors once a week.

We take allergies personally.

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