

Your essential guide

ACARIZAX®

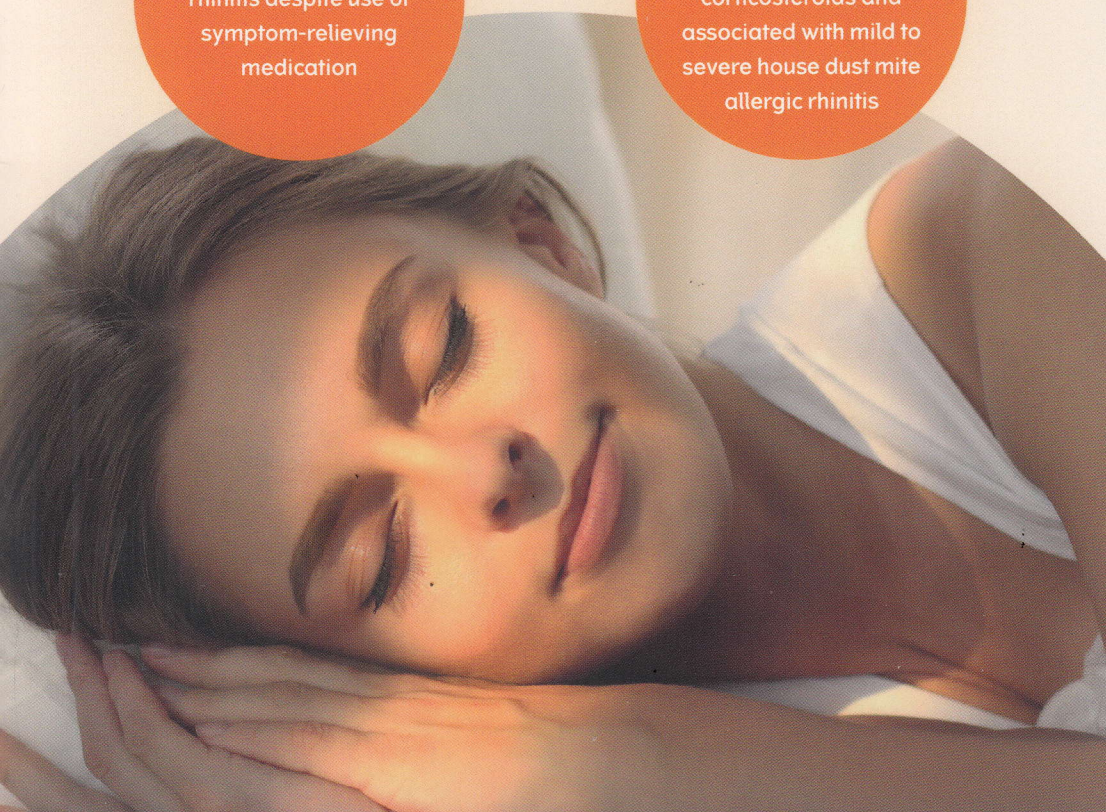
(Dermatophagoides pteronyssinus and Dermatophagoides farina)

**Allergy immunotherapy tablets
For adult patients sensitised to house dust mites (HDM)
with either:**

Persistent moderate
to severe HDM allergic
rhinitis despite use of
symptom-relieving
medication

Or

House dust mite
allergic asthma not well
controlled by inhaled
corticosteroids and
associated with mild to
severe house dust mite
allergic rhinitis

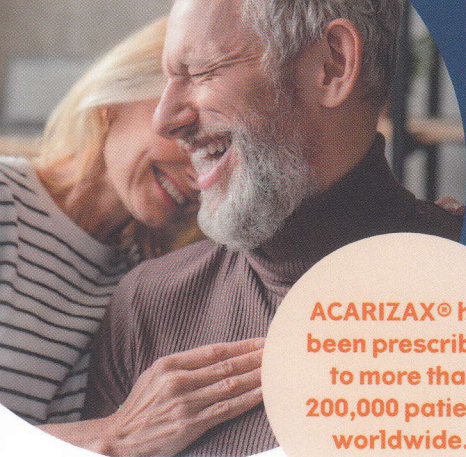


Please take the time to read this leaflet carefully, it has been created to give you helpful information in relation to taking Acarizax®. This leaflet should be read alongside the patient information leaflet that accompanies the medication.

If you have any questions or concerns, please speak to your healthcare professional.



Allergy solutions for life



ACARIZAX® has been prescribed to more than 200,000 patients worldwide.²

Hello

If you've been prescribed ACARIZAX® for house dust mite allergy, this guide is for you.

It covers the information you'll need to get the most from this treatment, and what to do if you experience any side effects from the treatment.

About ACARIZAX®

ACARIZAX® is used to treat house dust mite allergic rhinitis (inflammation of the lining of the nose) in adults aged 18-65, who have moderate to severe symptoms despite other medications. It's also used in adults aged 18-65 with house dust mite allergic asthma associated with house dust mite allergic rhinitis, whose symptoms are not well controlled by inhaled corticosteroids.¹

ACARIZAX® is referred to as a sublingual immunotherapy (or SLIT) – so you'll place a small, fast-dissolving tablet under your tongue each day.³ The tablets contain quality-controlled amounts of house dust mite allergen to help your immune system to build-up tolerance to house dust mites.¹



One tablet a day is the recommended dose, so one tablet a day is all you need – taking more than one tablet a day may increase the risk of a side effect.¹

Starting treatment



Your first dose should be taken under medical supervision so you can be monitored for side effects.



Read the patient information leaflet inside the packaging and follow the instructions carefully.



How it works

Your house dust mite (HDM) allergy is caused by your body's unnecessary immune response to HDMs (allergens). This means your immune system has wrongly identified HDMs as a threat, and is responding in unhelpful ways. These unhelpful responses are often called hypersensitivities and cause the unwanted symptoms that can affect how well you feel.⁴

ACARIZAX® is an allergen immunotherapy treatment (AIT) sometimes called desensitisation therapy.^{1,4} By regularly exposing your body to carefully controlled amounts of HDM allergens, it helps your body to build immunity patients can relate immunity to immunotherapy so this will help simplify the message. Over time this reduces your body's unhelpful responses to HDMs, which in turn reduces your symptoms, and helps you feel better.⁴

During AIT, the immune system's response changes. The changes are complex and take

time to happen. You should expect to see improvements in your symptoms in 8-14 weeks after starting treatment.^{1,4}

International treatment guidelines refer to a treatment period of 3 years for allergy immunotherapy to achieve disease modification. To get the best results with ACARIZAX® you should take your tablet every day for three years – even on days when you're not bothered by symptoms.¹

International treatment guidelines:



Immunotherapy is the only treatment which aims to treat the underlying cause of an allergy rather than just the symptoms.¹



Take one tablet a day for three years to achieve disease modification.¹

Remember to take one tablet every day

Taking your tablets at the same time every day e.g. when brushing teeth can help to make ACARIZAX® part of your daily routine. Alternatively, setting an alarm on your mobile phone can help you to remember.

How to take ACARIZAX®

The first time you take ACARIZAX®, your healthcare professional will be there to support you. They'll monitor you and treat any immediate side effects. They'll also give you advice on taking your tablets at home.¹



1 Always use dry fingers to remove the tablet from the blister card



3 Avoid swallowing for one minute



2 Immediately place the tablet under your tongue. It will dissolve quickly



4 Don't eat or drink anything else for another five minutes

Side effects

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

You should expect some mild to moderate local allergic reactions in the first few days. In most cases, any side effects start within five minutes of taking the tablet and only last a few minutes or hours. These should subside over 1-3 months as you continue treatment.⁶

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

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

Here are some possible side effects you may experience:

Very common (may affect more than 1 in 10 people):

- Irritating sensation in the throat
- Swelling of the mouth and lips
- Itching of the mouth and ears
- Airway infections

Common (may affect up to 1 in 10 people):

- Prickling sensation or numbness of the mouth or tongue
- Itching of the eyes
- Itching of the tongue and lips
- Swelling of the tongue or throat

- Inflammation, discomfort or burning sensation in the mouth
- Redness in the mouth or mouth ulcers
- Pain in the mouth
- Altered taste
- Stomach pain or discomfort
- Diarrhoea
- Feeling sick (nausea and vomiting)
- Pain when swallowing or difficulty in swallowing
- Symptoms of asthma
- Cough
- Shortness of breath
- Chest discomfort
- Indigestion and heartburn
- Hoarseness
- Tiredness
- Hives and itching of the skin

If any side effects are worrying you or causing you difficulties, you should always contact your healthcare team. They will decide if you need any medicines such as antihistamines to help relieve your side effects.

Please refer to the patient information leaflet found inside the packaging for further details about side effects.

Report your side effects

If you have any side effects, talk to your Health Care Professional. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly, via the Yellow Card Scheme, at www.yellowcard.mhra.gov.uk or at www.hpra.ie (Ireland)

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

Side effects should also be reported to ALK Medical Information on **0118 903 7940** or drugsafetyuk@alk.net

Do's and don'ts

Do's

Before taking ACARIZAX® tell your Health Care Professional if:^{1,6}

- ✔ You've previously had a severe allergic reaction to injection house dust mite allergy immunotherapy. It might mean you have an increased risk of a similar reaction to ACARIZAX®
- ✔ You're allergic (hypersensitive) to any of the substances in the ACARIZAX® tablet
- ✔ You have had a severe asthma attack in the last 3 months
- ✔ You have a mouth infection/inflammation, had recent dental work, (eg a tooth removed) or lost a tooth
- ✔ You have asthma and you have an infection in your nose, throat, larynx, trachea, bronchi or lungs, (ie in the respiratory tract)
- ✔ You have a severe allergy to fish
- ✔ You have an autoimmune disease or cancer
- ✔ You are pregnant

During your course of treatment:

- ✔ Take ACARIZAX® once a day, every day, even on days when you're not affected by your symptoms. This will help you build long-term tolerance to house dust mites^{1,6}
- ✔ If you forget to take ACARIZAX® at the usual time, take it later the same day but don't take more than one tablet on any one day - the risk of experiencing a side effect increases^{1,6}

If you go more than **7 days** between doses, please **contact your healthcare professional** for advice before restarting treatment.¹

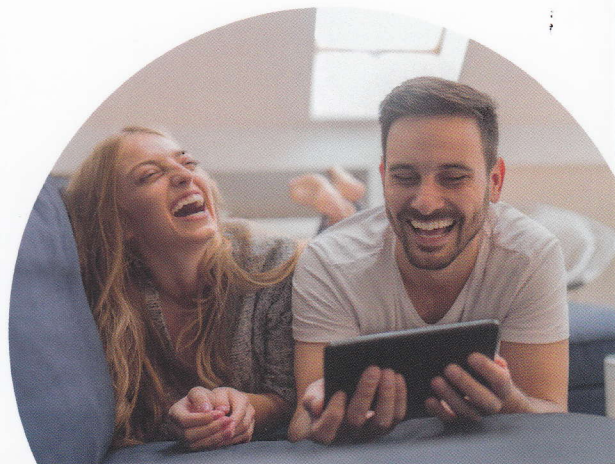


Contact your healthcare professional immediately if:¹

- ✘ You become pregnant
- ✘ You have an illness that affects your immune system
- ✘ Your asthma suddenly gets worse
- ✘ You experience a severe allergic reaction
- ✘ You are diagnosed with cancer
- ✘ Your mouth becomes severely inflamed
- ✘ You lose a tooth, had a tooth removed or other oral surgery
- ✘ You have persistent gastric symptoms such as difficulty swallowing or acid reflux

Don'ts

- ✘ If you forget to take your once-a-day dose, don't take a double dose the next day, there's an increased risk of side effects¹
- ✘ Take more than one tablet per day as this may increase side effects
- ✘ Forget to take your Acarizax® once-a-day, every day
- ✘ Stop or reduce your other medicines unless instructed to by your healthcare team





What to expect

ACARIZAX® will take a few months to work on your body's response to house dust mites (HDM). After this time your symptoms should improve. That means you may be able to gradually reduce the other medications you take for your HDM allergy.¹



In most cases, people start to feel better after taking ACARIZAX® once-a-day for 8-14 weeks.



Your doctor will stop your ACARIZAX® if you don't feel better during the first year of treatment.



Don't use ACARIZAX® to treat an asthma attack. Use your asthma medication as directed by your doctor. Seek medical attention immediately if your asthma suddenly gets worse.



To gain the full benefit from your treatment, take ACARIZAX® **once-a-day** as prescribed for three years.¹

References

1. ACARIZAX® Summary of Product Characteristics, May 2021
2. ALK 2019 Annual Report (p24)
3. <https://www.catalent.com/oral-dose/oral-technologies/orally-disintegrating-tablets/>
4. ALK Data on File 2021-227C 5. British Society for Immunology, Policy Briefing: Allergy <https://www.immunology.org/sites/default/files/Allergy%20briefing.pdf>
6. Acarizax® Patient Information Leaflet



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