

Package leaflet: Information for the user

ACARIZAX 12 SQ-HDM sublingual lyophilisate
For use in adults and adolescents (12-65 years of age)
Standardised allergen extract from House Dust Mites
(*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*)

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 ACARIZAX is and what it is used for
2. What you need to know before you take ACARIZAX
3. How to take ACARIZAX
4. Possible side effects
5. How to store ACARIZAX
6. Contents of the pack and other information

1. What ACARIZAX is and what it is used for

ACARIZAX contains an allergen extract from house dust mites. It comes in a form known as sublingual lyophilisates, which are like tablets but much softer and absorbed into the body by putting them under the tongue.

ACARIZAX is used to treat allergic rhinitis (inflammation of the lining of the nose) in adults and adolescents (12-65 years of age) and related allergic asthma, caused by house dust mites in adults (18-65 years of age). ACARIZAX works by increasing the immunological tolerance (your body's ability to cope) to house dust mites. The treatment may need to be taken for 8 to 14 weeks before you notice any improvement.

The doctor will check your allergic symptoms and do a skin prick test and/or take a blood sample in order to decide if ACARIZAX is a suitable treatment for you.

The first dose of ACARIZAX 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 with the doctor, any possible side effects you may have.

ACARIZAX is prescribed by doctors with experience in treating allergies.

2. What you need to know before you take ACARIZAX

Do not take ACARIZAX if:

- You are allergic to any of the excipients (other ingredients) in this medicine (listed in section 6).
- You have poor lung function (as assessed by your doctor).
- You have had a severe asthma worsening within the last three months (as assessed by your doctor).

- You have asthma and an ongoing airway infection, such as common cold, sore throat or pneumonia, on the day you are to take the first dose of ACARIZAX. Your doctor will delay the start of your treatment until you are better.
- You have an illness which affects the immune system, are taking medicines which suppress the immune system or have cancer.
- You have recently had a tooth taken out, other forms of mouth surgery, or have mouth ulcers or mouth infections. Your doctor may recommend delaying the start of the treatment or stopping treatment until your mouth has healed.

Warnings and precautions

Talk to your doctor before taking ACARIZAX if:

- You are being treated for depression with tricyclic antidepressants, mono amino oxidase inhibitors (MAOIs) or for Parkinson's disease with COMT inhibitors.
- You have previously had a severe allergic reaction to an injection of allergen extract of house dust mites.
- You have allergy to fish. ACARIZAX may contain trace amounts of fish protein. Available data have not indicated an increased risk of allergic reactions in patients with fish allergy.
- You experience severe allergic symptoms, such as difficulty in swallowing or breathing, changes in your voice, hypotension (low blood pressure) or feeling of a lump in the throat. Stop the treatment and contact your doctor immediately.
- Your asthma symptoms get noticeably worse than normal. Stop treatment and contact your doctor immediately.

If you have asthma, you should continue to use your regular asthma medication while starting treatment with ACARIZAX. Your doctor will tell you how to gradually reduce the asthma medication over time.

You should stop taking ACARIZAX and contact your doctor, if you experience severe or persistent heartburn or difficulty in swallowing, as these symptoms could be signs of allergic inflammation of the oesophagus.

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

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

Children and adolescents

Allergic rhinitis (inflammation of the lining of the nose):

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

Allergic asthma:

ACARIZAX is not intended for treatment of allergic asthma in children below 18 years of age.

Other medicines and ACARIZAX

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you are taking other medicines for your allergy symptoms such as antihistamines, asthma reliever medications or steroids, tell your doctor so you can be advised about their use while being treated with ACARIZAX. If you stop taking these medicines for your allergy symptoms you may experience more side effects of ACARIZAX.

ACARIZAX with food and drink

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

Pregnancy and breast-feeding

At present there is no experience of using ACARIZAX during pregnancy. Treatment with ACARIZAX 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.

At present there is no experience of using ACARIZAX during breast-feeding. However, no effects on the breast-fed infants are anticipated. Speak to your doctor about whether you may continue to take ACARIZAX while breast-feeding your infant.

Driving and using machines

Treatment with ACARIZAX has no or very little effect on the ability to drive or use machines. However, only you can judge if you feel you are being affected, therefore read all the information in this leaflet, especially section 4 'Possible side effects' and talk to your doctor or pharmacist if you are unsure.

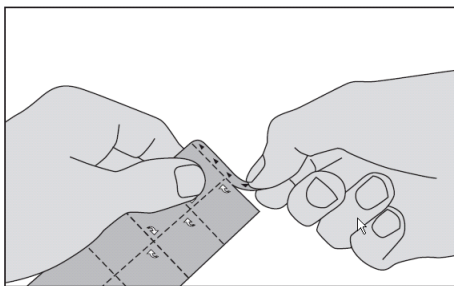
3. How to take ACARIZAX

Always take ACARIZAX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

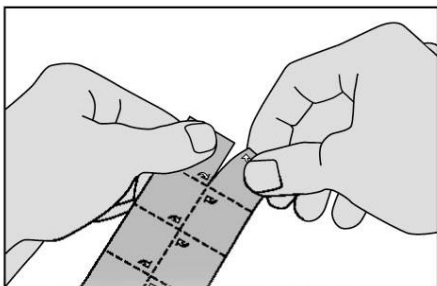
The usual dose is one lyophilisate daily. Your doctor will advise you for how long you should take ACARIZAX.

Use in adults and adolescents

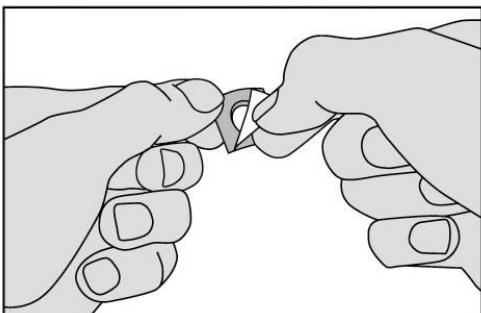
Make sure your hands are dry before handling the medicine. Take the medicine like this:



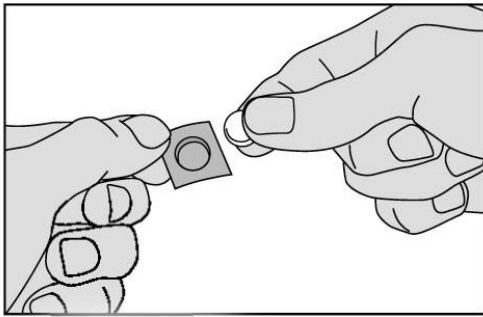
1. Tear off the strip marked with triangles at the top of the pack.



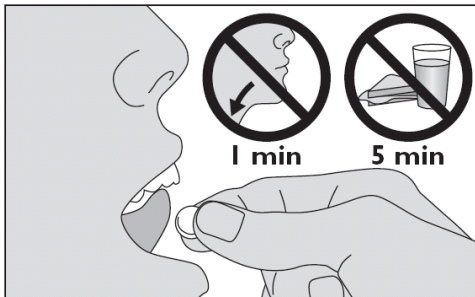
2. Tear a square off the pack along the perforated lines.



3. Do not force the medicine through the foil. Doing this may damage it because it breaks easily. Instead, fold back the marked corner of the foil and then pull it off.



4. Remove the medicine carefully from the foil and use it immediately.



5. Place the medicine under the tongue. Allow it to remain there until it has dissolved. Do not swallow for 1 minute. Do not eat or drink for at least 5 minutes.

If you take more ACARIZAX than you should

If you have taken too many lyophilisates you may experience allergic symptoms including local symptoms in the mouth and throat. If you get severe symptoms, contact a doctor or a hospital immediately.

If you forget to take ACARIZAX

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 ACARIZAX for more than 7 days you should contact your doctor before taking ACARIZAX again.

If you stop taking ACARIZAX

If you do not take this medicine as prescribed, 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 1-3 months.

Most serious side effects:

Uncommon (may affect up to 1 in 100 people):

- Serious allergic reaction

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

Possible other side effects:

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

Uncommon (may affect up to 1 in 100 people):

- Inflammation of the eyes
- Sensation of rapid forceful or irregular beating of the heart
- Ear discomfort
- Tightness in the throat
- Nasal discomfort, stuffy or runny nose, sneezing
- Blisters in the mouth
- Irritation of the oesophagus
- Sensation of something stuck in the throat
- Dizziness
- General discomfort
- Dry mouth
- Prickling sensation of the skin
- Red throat
- Tonsil enlargement
- Pain in the lip
- Lip ulcer
- Salivary gland enlargement
- Increased production of saliva

- Redness of the skin

Rare (may affect up to 1 in 1000 people):

- Rapid swelling of face or skin
- Allergic inflammation of the oesophagus (eosinophilic oesophagitis)

If any side effects are worrying you or causing you difficulties, you should contact your doctor who will decide if you need any medicines such as antihistamines to help relieve the side effects, you are suffering from.

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 to the HPRC via HPRC Pharmacovigilance: Website www.hpra.ie. By reporting side effects you can help provide more information on safety of this medicine.

5. How to store ACARIZAX

Keep out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What ACARIZAX contains

The active substance is standardised allergen extract from the house dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*. The activity per sublingual lyophilisate is expressed using the unit SQ-HDM. The activity of one sublingual lyophilisate is 12 SQ-HDM.

The other ingredients are gelatine (from fish), mannitol and sodium hydroxide (for pH adjustment).

What ACARIZAX looks like and contents of the pack

White to off-white circular sublingual lyophilisate marked with an impressed image on one side.

Aluminium blister cards with removable aluminium foil in an outer carton. Each blister card contains 10 sublingual lyophilisates.

Following pack sizes are available: 10, 30 or 90 sublingual lyophilisates.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

ALK-Abelló A/S
Bøge Allé 6-8
DK-2970 Hørsholm
Denmark

Manufacturer

ALK-Abelló S.A.
Miguel Fleta 19

28037 Madrid
Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium, Croatia, Germany, Hungary, Ireland, Luxembourg, Portugal, Romania, Slovenia, Spain:
ACARIZAX

This leaflet was last revised in May 2023.