

**Patient leaflet in accordance with the Pharmacists' Regulations**  
**(Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

**Acarizax**

**Tablets for use under the tongue**

**Active ingredients:** Standardized allergen extract from house dust mites 12 SQ-HDM

*Dermatophagoides pteronyssinus* 6 SQ-HDM

*Dermatophagoides farinae* 6 SQ-HDM

Inactive ingredients and allergens: see section 6 'Additional information'.

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

ACARIZAX is prescribed in special clinics by allergy and immunology specialists.

**1. What is this medicine intended for?**

ACARIZAX is used to treat adults (18-65 years of age) who have been diagnosed based on their medical history and whose skin prick tests for house dust mite were found positive and who have at least one of the following conditions:

- persistent, moderate to severe allergic rhinitis, caused by house dust mite allergy despite medication to relieve symptoms.
- allergic asthma, caused by house dust mite, that is not well controlled with corticosteroid inhalers, and is associated with mild to severe allergic rhinitis. Severity of the patient's asthma must be carefully diagnosed before starting treatment.

ACARIZAX is used to treat adolescents (12-17 years of age) whose skin prick tests for house dust mite were found positive and who have been diagnosed based on their medical history with persistent moderate to severe allergic rhinitis, despite medication to relieve symptoms.

**Therapeutic group:** allergen extract from house dust mites.

ACARIZAX works by increasing the immunological tolerance (your body's ability to cope with) to house dust mites. You may need to take the treatment for 8 to 14 weeks before you notice any improvement.

An immunology and allergy specialist 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.

Your first dose of ACARIZAX must be taken under medical observation. You must 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. This will also give you the chance to discuss with your doctor any possible side effect you may have.

ACARIZAX oral lyophilisate tablets look like ordinary tablets but are softer and are absorbed into the body by putting them under the tongue, lyophilisate tablets for use under the tongue (oral lyophilisate).

The activity of the dispersible table (oral lyophilisate) for use under the tongue is expressed in SQ-HDM units. There are 12 SQ-HDM in each tablet.

## **2. Before using this medicine**

### **Do not use this medicine if:**

- You are sensitive (allergic) to any of the other ingredients in this medicine (see 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 supposed 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.

### **Special warnings about using this medicine**

#### **Before you start treatment with ACARIZAX, tell your doctor if:**

- You are being treated for depression with tricyclic antidepressants, monoamine 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 an 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, 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 the 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 medications 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 esophagus.

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

Your doctor may decide to prescribe you with an epinephrine auto-injector for self-injection. This is a medicine that you can inject yourself if you get a severe allergic reaction after taking ACARIZAX. In this case, your doctor will teach you how to use the auto-injector to inject yourself correctly.

### **Children and adolescents**

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

ACARIZAX is used to treat allergic rhinitis in adolescents (12-17 years old).

ACARIZAX is not intended for the treatment of allergic rhinitis in children under 12 years old.

Allergic asthma:

ACARIZAX is not intended for treatment of allergic asthma in children and adolescents under 18 years old.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.** 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 using them while being treated with ACARIZAX. If you stop taking these medicines for your allergy symptoms you may experience more side effects of ACARIZAX.

### **Taking ACARIZAX with food and drink**

Avoid food and drink for 5 minutes after taking this medicine.

### **Pregnancy and breastfeeding**

At present there is no experience with ACARIZAX use during pregnancy. Do not start treatment with ACARIZAX during pregnancy. If you become pregnant during treatment, check with your doctor whether you should continue taking the treatment.

At present there is no experience with ACARIZAX use during breastfeeding. However, no effect on the breastfed babies is anticipated. Check with your doctor whether you can continue to take ACARIZAX while breastfeeding your baby.

### **Driving and using machines**

Treatment with ACARIZAX has no effect or very little effect on the ability to drive or use machines. However, only you can judge if you feel any effect, so read all the information in this leaflet, especially section 4 'Side effects' and talk to your doctor or pharmacist if you are not sure.

### **Important information about some of this medicine's ingredients**

This medicine contains less than 1 mmol (23 mg) sodium per dose, therefore, it is considered as essentially sodium-free.

### **3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The usual dose is one dispersible tablet a day. Your doctor will advise you how long you should take ACARIZAX.

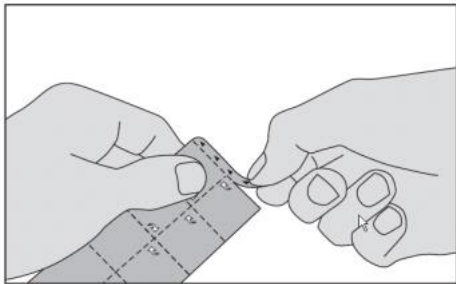
Your first dose of ACARIZAX must be taken under medical observation. You must stay under medical observation for at least half an hour after taking the first dose.

You may need to take this treatment for 8 to 14 weeks before you notice any improvement.

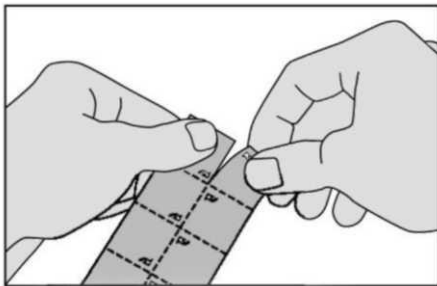
**Do not exceed the recommended dose.**

How to use this medicine in adults and adolescents:

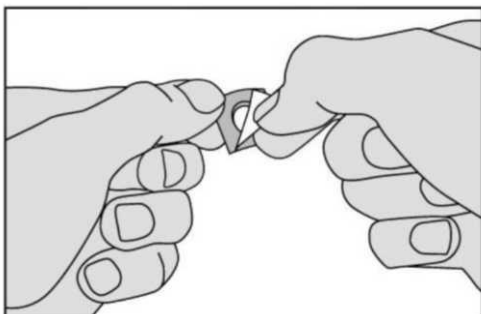
Make sure your hands are dry before handling the medicine. Take the medicine like this:



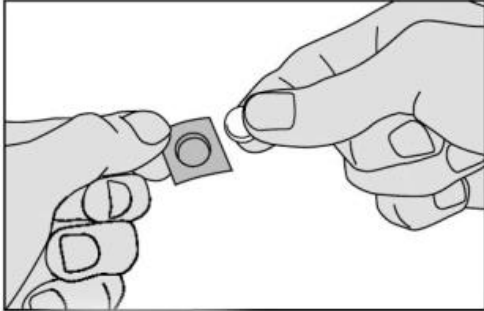
1. Tear off the strip marked with triangles on the end of the blister.



2. Tear off one square along the perforated lines.



3. Do not force the medicine through the foil. Doing this may damage it because it breaks easily. To open, peel back the marked corner of the foil and then pull it off all the way.



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



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

Do not crush/split/chew the tablet.

#### **If you take too much ACARIZAX**

If you have taken too many dispersible tablets you may experience allergic symptoms including local symptoms in the mouth and throat. If you get severe symptoms, such as swelling (angioedema), difficulties swallowing, difficulties breathing, voice changes, or sensation of congestion in the throat, see a doctor or go to a hospital immediately.

If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

#### **If you forget to take ACARIZAX**

If you forget to take a dose, take it later in the day when you remember. Do not take a double dose that day to make up for the forgotten dose.

If you have not taken ACARIZAX for more than 7 days, 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.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## **4. Side effects**

Like with all medicines, using ACARIZAX may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The side effects may be an allergic response to the allergen in the medicine. 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.

### **The most serious side effects are:**

#### **Uncommon side effects (affect up to 1 in 100 people):**

- Serious allergic reaction

Stop taking ACARIZAX and contact your doctor or go to 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

**Additional side effects:**

Very common side effects (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 side effects (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
- diarrhea
- 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 side effects (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 esophagus
- sensation of something stuck in the throat
- dizziness
- general discomfort
- dry mouth
- prickling sensation of the skin
- red throat
- enlarged tonsils
- pain in the lips
- lip ulcer
- enlarged salivary gland
- increased production of saliva
- redness of the skin

Rare side effects (affect up to 1 in 1,000 people):

- rapid swelling of the face or skin
- allergic inflammation of the esophagus (eosinophilic esophagitis)

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

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

**Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the blister and carton. The expiry date refers to the last day of that month.

**Storage conditions:** Store below 25°C.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

## **6. Additional information**

**In addition to the active ingredients, this medicine also contains:**

gelatin (from fish), mannitol, sodium hydroxide (for pH adjustment).

**What the medicine looks like and contents of the pack:**

lyophilized white-cream tablets.

This medicine is available in pack sizes of 10, 30 and 90 tablets. Each blister card contains 10 tablets.

Not all pack sizes may be marketed.

**Registration holder's name and address:** Trupharm Marketing 1985 Ltd. POB 8105, Netanya.

**Manufacturer's name and address:**

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

The leaflet was revised in July 2022 according to MOH guidelines

Registration number of the medicine in the Ministry of Health's National Drug Registry: 165-50-35659

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