

ACARIZAX[®] 12 SQ-HDM SUBLINGUAL LYOPHILISATE

Standardised allergen extract from House Dust Mites
(6 SQ-HDM Dermatophagoides pteronyssinus and 6 SQ-SDM Dermatophagoides farinae)

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What ACARIZAX[®] 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).

How product name works

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.

Before you use ACARIZAX[®]

When you must not use it

Do not take this medicine if:

- You are allergic to active ingredients or any other ingredients of this medicine (listed in Product Description)
- 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.

Before you start to use it

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 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. If you experience persisting heartburn or difficulty in swallowing you should contact your doctor. 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.

Pregnancy and lactation

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 whether you may

continue to take ACARIZAX® while breast-feeding your infant.

- Things to be careful of

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

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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.

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®.

How to use ACARIZAX®

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

The usual dose is one lyophilisate daily.

- When to use it

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.

- How long to use it

Your doctor will advise you for how long you should take ACARIZAX®.

- If you forget to use it

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 use too much (overdose)

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.

While you are using ACARIZAX®

- Things you must do

Make sure your hands are dry before handling the medicine.

- Things you must not do

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.

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.

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 or throat
- Difficulties in swallowing
- Difficulties in breathing
- Voice changes
- Hypotension (low blood pressure)
- Feeling of fullness in the throat (like a swelling)

Possible other side effects:

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

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

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

- Prickling sensation or numbness of the mouth or tongue
- Eye or ear itching
- Itching of the tongue and lips
- Swelling of the lips, tongue or throat
- Dry mouth, inflammation or burning sensation in the mouth
- Stomach pain or discomfort
- Diarrhoea
- Feeling sick (nausea)
- Pain when swallowing or difficulty in swallowing
- Shortness of breath
- Chest discomfort
- Indigestion
- Hoarseness

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

- Tightness in the throat
- Nasal discomfort, stuffy or runny nose, sneezing
- Blistering of the mouth, redness in the mouth or mouth ulcers
- Tongue inflammation
- Altered taste
- Irritation of the oesophagus
- Vomiting

- Sensation of something stuck in the throat

- Dizziness

- Tiredness or general discomfort

- Itching of the skin

- Rash

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ACARIZAX®

- Storage

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.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

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

- Ingredients

The active substance is standardised allergen extract from the house dust mites: 6 SQ-HDM Dermatophagoides pteronyssinus and 6 SQ-HDM Dermatophagoides farinae. The activity per sublingual lyophilisate is expressed using the unit SQ-HDM. The activity of one sublingual lyophilisate is 12SQ-HDM.

- Inactive ingredients

- gelatine (from fish),
- mannitol and
- sodium hydroxide.

- MAL number(s):

MAL18086126ACRZ

Manufacturer

Manufacturer:

Catalent UK Swindon Zydis Ltd
Frankland Road, Blagrove,
Swindon, Wiltshire, SN5 8RU,
United Kingdom

Released by:

ALK-Abelló S.A
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Product Registration Holder

Name and address

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