



Pr **ACARIZAX™**

Standardized Allergen Extract,
House Dust Mites (*D. farinæ* and *D. pteronyssinus*)



**Your guide to using ACARIZAX™
for the treatment of allergy to house dust mites.**


IMPORTANT:

See **page 6** for what ACARIZAX™ does
See **pages 8–10** for how to take ACARIZAX™

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WHAT IS AN ALLERGIC REACTION?

The immune system's job is to protect your body from invaders, such as viruses and bacteria. In some people, the immune system can become oversensitive. When this happens, the body thinks that normal substances in the environment are harmful. Upon contact with these substances, known as allergens, the immune system produces an allergic reaction.

Words to help with this section:

Allergen: A normal substance in the environment that causes an allergic reaction in people who are sensitive to it.

Allergic reaction: A reaction of the immune system that occurs when your body comes in contact with substances you are sensitive to.

Immune system: A system that protects your body from disease and infections.

WHAT IS HOUSE DUST MITE ALLERGY?

You may already know the answer to this question. However, you may want to explain the cause of your house dust mite allergy to your family or others. If so, we hope that you find the following helpful.

House dust mites are tiny bugs that live in house dust and are too small to be seen. They live in places like furniture, bedding, and carpets and prefer humid temperatures. Exposure to house dust mites can occur any time of the year and can cause allergy symptoms in those who are oversensitive to house dust mites.

These symptoms may differ from person to person, depending on how the body responds to house dust mite allergen.



1. Dust contains house dust mites and their debris
2. The proteins in this "dust mite debris" can become airborne
3. The immune cells in the lining of your nose, mouth and throat react to the allergen, causing the signs and symptoms of house dust mite allergy

WHAT ARE THE SYMPTOMS OF DUST MITE ALLERGY?

If you have a house dust mite allergy, you probably know some of the symptoms that can occur when you come in contact with house dust mite allergens. For example, when you are in dusty indoor environments, in bed, or when the heat is on during the colder months.

THE MOST COMMON SYMPTOMS OF HOUSE DUST MITE ALLERGY INCLUDE:

- Runny nose
- Itchy nose and eyes
- Sneezing
- Watery eyes
- Red eyes
- Nasal congestion



WHAT IS ACARIZAX™?

ACARIZAX™ is a sublingual allergy tablet that contains an allergen extract used to help treat your allergy caused by house dust mites, characterized by rhinitis with or without conjunctivitis.

ACARIZAX™ is to be prescribed only by doctors who are trained and experienced in the treatment of allergic diseases.

ACARIZAX™ reduces symptoms by helping to make you less sensitive to house dust mite allergens.

WHO IS ACARIZAX™ FOR?

ACARIZAX™ is used for the treatment of adults 18 to 65 years of age with a history of allergy to house dust mites. It has not been tested in patients younger than 12 years of age, and the efficacy and safety have not been well established in subjects between the ages of 12 and 18, and over 64.

You should not take ACARIZAX™ if you:

- Have severe or unstable asthma
- Have ever had a serious allergic reaction to house dust mite allergy shots, tablets or drops
- Are taking beta-blockers, a medicine for heart conditions, such as high blood pressure
- Have any swelling or sores in your mouth or have recently had any mouth injury or mouth surgery
- Have been diagnosed with a rare condition called eosinophilic esophagitis
- Are allergic or hypersensitive to any of the other ingredients of ACARIZAX™

WHAT ARE THE INGREDIENTS IN ACARIZAX™?

- The active ingredient in ACARIZAX™ is Standardized Allergen Extract of house dust mites *D. farinae* and *D. pteronyssinus*
- ACARIZAX™ does not contain lactose
- The other non-medicinal ingredients in ACARIZAX™ include: fish gelatin, mannitol and sodium hydroxide

Words to help with this section:

Hypersensitivity: An extreme reaction produced by the immune system (i.e., an allergic reaction when you come in contact with something you are sensitive to).

Sublingual tablet: A form of medication that is taken by placing a pill under your tongue where it dissolves.

HOW DO I TAKE ACARIZAX™?

ACARIZAX™ should be taken **once a day** as one tablet for as long as your doctor tells you to take it.

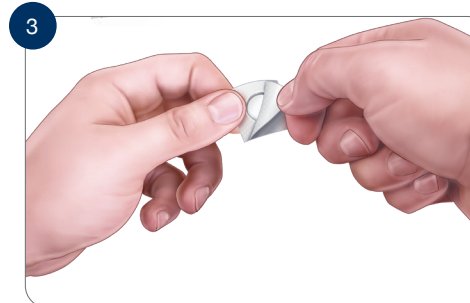
The first dose of ACARIZAX™ should only be taken in the doctor's office:

- After taking the first dose, you will be watched for 30 minutes by a healthcare professional for symptoms of a serious allergic reaction

- Your doctor may prescribe medicines for you to take in case you have a serious allergic reaction

ACARIZAX™ can be started **any time of the year**. After the first dose, you may take ACARIZAX™ at home.

ARE THERE SPECIAL INSTRUCTIONS FOR TAKING ACARIZAX™?



Do not use food or water to take the tablet.

1. Tear off the strip marked with triangles at the top of the blister pack
2. Tear a square off the blister pack along the perforated lines
3. Remove the tablet from the package with dry hands by carefully removing the foil

(Do not force the tablet through the foil. It may become damaged as it easily breaks. Instead, fold back the marked corner of the foil and then pull it off.)


Take it right away.

4. **Place the tablet under the tongue** and allow it to remain there for a few seconds until it dissolves

Do not swallow during the first minute and do not eat or drink for 5 minutes.

Wash your hands after handling the tablet.

This medicine has been prescribed for you. Do not give it to anyone else. It may harm them, even if their symptoms are the same as yours.



WHAT SHOULD I TELL MY DOCTOR BEFORE OR AFTER TAKING ACARIZAX™?

Before you begin treatment with ACARIZAX™, your allergy will be confirmed by a doctor who will perform skin and/or blood tests.

Tell your doctor and pharmacist about all the medicines you take, including prescription and nonprescription medicines, vitamins, minerals, natural supplements or alternative medicine. Your doctor will tell you if it is safe to take other medicines while you are using ACARIZAX™. However, no drug interaction studies have been done in patients taking ACARIZAX™.

Before you take ACARIZAX™, tell your doctor if you:

- Have ever had a serious allergic reaction to allergy shots, tablets or drops
- Have worsening asthma symptoms or breathing problems
- Have an airway infection, such as a common cold, sore throat or pneumonia
- Are pregnant or could become pregnant
- Are breast-feeding or plan to breast-feed. It is not known if ACARIZAX™ will pass into breast milk
- Have diseases which affect the immune system, such as autoimmune diseases, immune complex diseases or (severe) immune deficiency diseases
- Have malignant diseases such as cancer

WHAT IF I MISS A DOSE?

If you miss a dose, return to your normal schedule the next day. Do not double up to make up for the forgotten dose.

WHAT IF I TAKE TOO MUCH?

Taking more than one ACARIZAX™ tablet in one day can cause severe allergic reactions. If you take too much, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

HOW DO I STORE ACARIZAX™?

- ACARIZAX™ should be stored at room temperature (do not store above 25°C)
- You should store ACARIZAX™ in its original package
- Keep package and tablets dry
 - Medicines should not be kept in a bathroom or kitchen cabinet
- Keep out of reach of children



WHAT ARE THE SIDE EFFECTS WITH ACARIZAX™?

ACARIZAX™ can cause side effects, including serious side effects. The side effects usually happen early in treatment, but can happen even if you have been taking ACARIZAX™ for months.

The most common side effects of ACARIZAX™ include:

- Throat irritation
- Itching of the ears and/or mouth
- Tingling and/or burning of the mouth
- Swelling of the mouth including lips and/or tongue

Stronger allergic reactions to ACARIZAX™ include:

- Swelling of the throat, mouth or tongue
- Difficulty swallowing or breathing
- Asthma attack/wheezing
- Hives/itchy rash
- Voice changes (hoarse voice or trouble speaking)
- Rapid heart rate
- Low blood pressure
- Fainting

It is common for patients to experience mild or moderate local allergic reactions with ACARIZAX™ such as an itchy mouth or sore throat. Serious life-threatening allergic reactions which require immediate medical attention may occur in patients treated with ACARIZAX™.

If you experience these symptoms, contact your doctor immediately and get emergency treatment. Do not take any more doses until your doctor tells you to.

Serious side effects and what to do about them				
Symptom/effect		Talk to your healthcare professional		Stop taking drug and get immediate help
		Only if severe	In all cases	
Very Common	Swelling in the throat	✓		
	Swollen tongue	✓		
Common	Swelling in the mouth	✓		
	Trouble swallowing			✓
	Chest discomfort	✓		
	Itching all over your body	✓		
	Hives all over your body	✓		
Uncommon	Throat tightness			✓
	Severe allergic reactions			Seek emergency help immediately
	Shortness of breath			

Refer to the Consumer Information leaflet provided with ACARIZAX™ for more complete information on side effects and what to do about them.
This is not a complete list of side effects. For any unexpected effects while taking ACARIZAX™, contact your doctor or pharmacist.

TIPS TO HELP MANAGE HOUSE DUST MITE ALLERGIES.

Below is a list of ways to help you to manage house dust mite allergies.

Check off the ones you are doing now. Circle those that you might want to remember:

- ☐ Don't hang heavy drapes or other items that are prone to collecting dust
- ☐ Remove all carpets from the sleeping area
- ☐ Clean often to keep dust build-up to a minimum
- ☐ Cover mattresses and pillows with mite-proof encasings to reduce house dust mites

This material is intended to be used by patients who have been prescribed ACARIZAX™



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