

Allergic to house dust mite (HDM)*

ACARIZAX[®] 12-SQ HDM SLIT-Tablet – A new solution to house dust mite allergy now offers more effective control of allergic rhinitis and/or allergic asthma¹

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA on September 2023, and includes "Important Safety Information for Patients".



You are on the right track

You have been given this guide because your doctor has recommended 12 SQ-HDM SLIT-Tablet for you. This guide answers some common questions about 12 SQ-HDM SLIT-Tablet, but does not replace the advice of your healthcare professional.

If you have any question about your condition or its treatment, please speak to your doctor.

“It is advised to be read carefully before prescribing/administering the product.”

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What is house dust mite allergy?

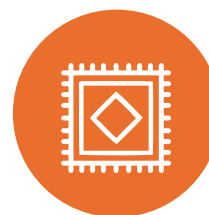
- Allergies occur when a person's immune system reacts to substances that are normally harmless. These substances are called allergens. Allergic diseases can include asthma, allergic rhinitis and eczema, as well as food, insect and drug allergies.²
- HDM* are common causes of allergies and are often found in household furniture such as:³



Mattresses



Sofas



Carpets

- House dust mites are small creatures that can't be seen with the naked eye. When their waste products come into contact with a person's nose, lungs or eyes, an allergic reaction may occur. This allergic reaction may present as allergic rhinitis (mainly affecting the nasal passage) and/or allergic asthma (mainly affecting the lower airway). Together, allergic rhinitis and allergic asthma are known as "respiratory allergy".²

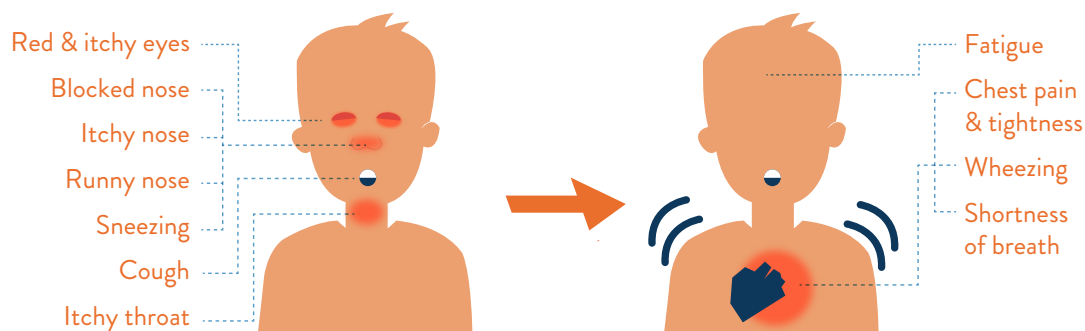


DID YOU KNOW?

People who are sensitive to house dust mites usually experience symptoms of respiratory allergy throughout the year.²

HDM* respiratory allergy-symptoms

HDM* symptoms typically include.^{3,4}



Patients with respiratory allergic disease caused by house dust mite allergy are likely to experience:^{3,4}

- An increased risk of developing allergic asthma if they have allergic rhinitis as a single condition.
- A decrease in lung function if they have asthma.
- Asthma that is more likely to be moderate or severe.
- A greater risk of recurrent asthma exacerbation.

DID YOU KNOW?

Patients with poorly controlled Allergic Rhinitis may develop Allergic Asthma.^{3,4}

How are HDM* allergies diagnosed?³



Skin prick test



Specific IgE blood test

How is house dust mite respiratory allergy treated?^{5,6,7}

Allergen avoidance

It can be difficult to avoid house dust mites altogether, but measures such as dust mite, resistant covers for bedding, and washing bedding in hot water (60°C) may help to reduce exposure.

Medicines to control symptoms

These medicines may help to reduce the symptoms of allergy (such as runny or blocked nose) but do not change the way the body reacts to the allergen. This means your symptoms may return if you stop taking them. Some examples of these medicines include anti-histamines and corticosteroid nasal sprays. These medicines may not be effective for everyone, and many people with persistent respiratory allergy find that they cannot get enough symptom relief with these medicines alone.

Immunotherapy

House dust mite immunotherapy works by increasing your body's tolerance to house dust mite allergens (a process known as desensitization). It involves administering controlled amounts of house dust mite allergen extract regularly over several years to help build up tolerance.

Immunotherapy is the only treatment that targets the underlying cause of house dust mite allergy, not just the symptoms of allergic disease. By allowing the immune system to become tolerant to these allergens, immunotherapy can help reduce the use of allergy-related medication, and potentially provide a long-term effect, even after your treatment ends.

Treatment of HDM Respiratory Allergy



Allergen Avoidance³

Some measures to avoid house dust mites include:

- Using dust mite-resistant bedding covers.
- Washing bedding in hot water (60°C).
- Vacuuming with a high-efficiency particulate air (HEPA) filter.

✔ Reduce exposure to house dust mites.

✘ Unable to completely prevent exposure to house dust mites.

✘ Inconvenient to implement in the long-term.



Medications

Medicines like antihistamines and corticosteroid nasal sprays can help reduce the symptoms of allergy.

✔ Relieves allergy symptoms such as runny or blocked nose.

✘ Symptoms may return once medication is stopped.

✘ Does not treat the underlying cause of house dust mite allergy.



Allergen Immunotherapy (AIT)^{5,6}

AIT involves administering controlled amounts of HDM* allergen extract regularly to increase the body's tolerance to HDM*.

✔ AIT targets the underlying cause of house dust mite allergy.

✔ Reduces / stops symptoms after treatment is stopped.

✔ Unlike other medication for chronic health conditions where treatment can last a lifetime, you only need to complete AIT treatment for 3 years.

You can expect an **improvement** in your symptoms 8-14 weeks after you have started taking 12 SQ-HDM SLIT-Tablet.¹

What is 12 SQ-HDM SLIT-Tablet?¹

- Is an **allergy immunotherapy (AIT)**.
- Is a **fast-dissolving sublingual tablet for HDM*** respiratory allergy to receive a market authorization.
- **Contains standardized allergen extract** from house dust mites (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*).



Dermatophagoides pteronyssinus



Dermatophagoides farinae

What is 12 SQ-HDM SLIT-Tablet used for?¹

12 SQ-HDM SLIT-Tablet is indicated in:

- **Adults (18-65 years)** diagnosed by **clinical history** and **a positive test of HDM sensitisation** (skin prick test and/or specific IgE) with at least one of the following conditions:
 - ✓ persistent moderate to severe HDM **Allergic Rhinitis** despite use of symptom-relieving medication.
 - ✓ HDM **Allergic Asthma** not well controlled by inhaled corticosteroids and associated with mild to severe HDM allergic rhinitis.
- **Adolescents (12-17 years)** diagnosed by **clinical history** and **a positive test of HDM sensitisation** (skin prick test and/or specific IgE) with persistent moderate to severe HDM **Allergic Rhinitis** despite use of symptom-relieving medication.

How 12 SQ-HDM SLIT-Tablet works?^{1,7,8,9}

- 12 SQ-HDM SLIT-Tablet works by **increasing the immunological tolerance** (your body's ability to cope) to house dust mites.
- 12 SQ-HDM SLIT-Tablet is an allergy immunotherapy, which is a long-term treatment that **targets the underlying** cause of house dust mite allergy, not only the symptoms of allergic disease.
- **The doctor will check your allergic symptoms** and do a skin prick test and/or take a blood sample in order **to decide** if 12 SQ-HDM SLIT-Tablet is a suitable treatment for you.

What are the benefits you get from 12 SQ-HDM SLIT-Tablet?^{1,8,9}



Proven Efficacy

- Reduces symptoms of allergic rhinitis
- Reduces asthma severity and risk of exacerbation
- Reduces need for symptom relieving medications



Convenient

- Does not require refrigeration
- Easy to bring along when travelling



Easy to Administer

- Fast-dissolving tablet
- Does not require up-dosing



High manufacturing standards

- Every tablet contains high fixed concentrations of the HDM* major allergens



Cost-effective

- Reduces the need for symptom relieving medications in the long-term



Proven Safety Profile

- Well-tolerated and safe treatment, with mild to moderate local side effects

How to take 12 SQ-HDM SLIT-Tablet?^{1,8,9}

No special storage is needed.



- The usual dose is **one sublingual tablet once per day**. Your doctor will advise you for how long you should take 12 SQ-HDM SLIT-Tablet.
- One 12 SQ-HDM SLIT-Tablet is **placed under the tongue**, where it rapidly dissolves.



- Your doctor will give you the **first tablet** of 12 SQ-HDM SLIT-Tablet **under medical supervision**, and monitor you for at least 30 minutes.
- You should **take** 12 SQ-HDM SLIT-Tablet **exactly as your doctor has told you**. You should check with your doctor, health care provider or pharmacist if you are not sure.



- These sublingual tablets are quick and simple way for you to take immunotherapy at home or at work so your **treatment can be incorporated into your busy daily life**.

12 SQ-HDM SLIT-Tablet administration instructions^{1,8,9}



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



Tear a square off the pack along the perforated lines.



To remove the tablet, fold back the marked corner of the foil and pull it off.



Remove the tablet carefully from the foil, with **dry hands**.



Place the tablet **under the tongue**, allowing it to remain there until it has fully dissolved.



Do not swallow for 1 minute and do not eat or drink for at least 5 minutes.

Please make sure you **follow the directions** given to you by your **doctor**.

Do's and don'ts for taking 12 SQ-HDM SLIT-Tablet^{1,8,9}

The tablet dissolves very quickly, and that need to happen in your mouth not on your hands!



- **Wash and dry** your hands before handling 12 SQ-HDM SLIT-Tablet.



- **Continue** to take 12 SQ-HDM SLIT-Tablet for as long as your doctor tells you (treatment may continue for several years).



- **Tell** your doctor about all medicines you are taking.



- **keep** the blister card next to your toothbrush so that you remember and **wait at least 5min after taking** the tablet before cleaning your teeth.



- **Bend** the perforation line below the strip of arrows backwards and forwards- this makes it easier to break off- and tear it off in the direction of the arrows.



- **Don't use scissor** to cut the tablet from blister **or force** the tablet through the foil packaging, as it may damage the tablet.



- **Don't swallow** for 1 minute after the tablet dissolves.



- **Don't eat** or drink for 5 minutes after taking 12 SQ-HDM SLIT-Tablet.

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 12 SQ-HDM SLIT-Tablet. Part of your daily routine. Alternatively, setting an alarm on your mobile phone can help you to remember.



Don't use 12 SQ-HDM SLIT-Tablet to treat an asthma attack. Use your asthma medications as instructed by your doctor. Seek medical attention immediately if your asthma suddenly gets worse.

When will I start to feel better?⁸

12 SQ-HDM SLIT-Tablet works by increasing your body's tolerance to the HDM allergen, and gradually reduces or stops your allergic symptoms.



8-14
weeks

- Response to treatment varies from patient to patient, and you may need to take 12 SQ-HDM SLIT-Tablet daily for **at least 8-14 weeks** before you start to see an improvement in symptoms.
- **You will continue to see benefits over time.**

How long should I continue taking 12 SQ-HDM SLIT-Tablet?⁸

- **International treatment guidelines** recommend taking the tablet for a **minimum of 3 years** to achieve the full effect of treatment, or disease modification.



Do not stop taking the tablet **without consulting your doctor**, even if you feel better.

What will happen if you stop 12 SQ-HDM SLIT-Tablet?⁸

- **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 12 SQ-HDM SLIT-Tablet, **ask your doctor, health care provider or pharmacist.**

DID YOU KNOW?

By staying on treatment, you will increase your likelihood to live a life free of allergy.

What are the most common side effects with 12 SQ-HDM SLIT-Tablet?^{1,8,9}

- Like all medicines, 12 SQ-HDM SLIT-Tablet can cause side effects, although not everybody gets them but they are a sign that your immune system is responding.
- Side effects are usually mild to moderate in intensity and **subside when you persist with treatment as your body builds tolerance.**
- Your doctor will give you the first tablet under medical supervision and then monitor you for at least 30 minutes. This gives you the opportunity to discuss possible side effects with your doctor.

Most Common Side Effects:

- Irritating sensation in the throat.
- Mouth oedema.
- Itching of the mouth and ears.

Most common side effects include:



Typically, adverse reactions start within 5 minutes of administration and abate minutes to hours after intake.
Side effects typically occur at the start of treatment and subside within days or weeks.

- **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.
- **If you notice any adverse events not listed in the leaflet**, tell your doctor, health care provider or pharmacist.
- **If you get any side effects that are serious and develops rapidly**, contact a doctor immediately.

Tips to manage side effects⁹



- **Drink some water before** you take the sublingual tablet.



- **Place an ice cube** under your tongue, **5 minutes after** you have taken the tablet.



- **Eat and drink after 5 min** from taking the sublingual tablet as it may ease symptoms.



- **Ask your doctor** if you **can take an antihistamine** before taking the sublingual tablet (to be effective, antihistamine should be taken at least one hour beforehand).

What you should know about 12 SQ-HDM SLIT-Tablet during pregnancy and breast-feeding?^{1,8,9}

- There is no experience of using 12 SQ-HDM SLIT-Tablet during pregnancy.
- Treatment with 12 SQ-HDM SLIT-Tablet 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.
- No effects on the breast-fed infants are expected. **Speak to your doctor** whether you may continue to take 12 SQ-HDM SLIT-Tablet while breast-feeding your infant.

Don't initiate 12 SQ-HDM SLIT-Tablet if:^{1,8,9}

- You are **allergic** to any of the excipients (other ingredients) in this medicine.
- 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 are **pregnant**.
- You have an **illness** which **affects your immune system** or have **cancer**.



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

Consider special care with 12 SQ-HDM SLIT-Tablet if:^{1,8,9}

- You are being **treated for depression with tricyclic antidepressants**, mono aminooxidase 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 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 a doctor immediately.
- Your **asthma symptoms get noticeably worse than normal**. Stop treatment and contact a doctor immediately.
- Your doctor will delay the start of your treatment until you are better or healed if:

1-**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 12 SQ-HDM SLIT-Tablet.

2-You have recently had a **tooth taken out**, other **forms of mouth surgery**, or have **mouth ulcers or mouth infections**.

What to do if you forget to take 12 SQ-HDM SLIT-Tablet?^{1,8,9}

- 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 12 SQ-HDM SLIT-Tablet for **more than 7 days** you should **contact your doctor** before taking 12 SQ-HDM SLIT-Tablet again.

3 useful tips to remember to take 12 SQ-HDM SLIT-Tablet



Make it part of your daily routine like cleaning your teeth.



Set up a reminder / alert on your phone.



Leave yourself reminder notes.

What should you keep in mind?^{1,8,9}

- Be sure to **follow 12 SQ-HDM SLIT-Tablet administration instruction** (page 9).
- Take in consideration **the do's and don'ts** (page 10).
- **No titration** is needed.
- **No dose adjustment** is needed.
- Treatment with 12 SQ-HDM SLIT-Tablet has **no or very little effect on the ability to drive or use machines**.
- If you have asthma, you should continue to use your regular asthma medication while starting treatment with 12 SQ-HDM SLIT-Tablet. **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 localized allergic reactions during your treatment. If it is severe, **talk to your doctor to see if you need any anti-allergic medicines** such as antihistamines.

References

- 1- 12 SQ-HDM SLIT-Tablet Product Monograph.
- 2- <http://www.straitstimes.com/singapore/health/dangers-of-dust-mites-6-things-to-know-about-these-tiny-bugs-lurking-in-your-home>. Published May 17, 2016.
- 3- Dust Mite Allergy. Updated by Asthma and Allergy Foundation of America. Available from: <https://www.aafa.org/dust-mite-allergy>. Accessed on 17 December 2019.
- 4- Settipane, Russell A. "Complications of allergic rhinitis." Allergy and Asthma Proceedings. Vol. 20. No. 4. Oceanside Publications, 1999.
- 5- Cipriani, Francesca, Elisabetta Calamelli, and Giampaolo Ricci. "Allergen avoidance in allergic asthma." *Frontiers in pediatrics* 5 (2017): 103.
- 6- Calderón, Moisés A., et al. "House dust mite respiratory allergy: an overview of current therapeutic strategies." *The Journal of Allergy and Clinical Immunology: In Practice* 3.6 (2015): 843-855.
- 7- What do you need to know about Allergy tablets? Available from: <https://www.aaaai.org/conditions-and-treatments/library/allergy-library/allergy-tablets>. Accessed on 19 December 2019.
- 8- 12 SQ-HDM SLIT-Tablet oral lyophilisate Local Summary of Product Characteristics Date of revision: May 2022.
- 9- 12 SQ-HDM SLIT-Tablet Local Patient Information Leaflet Date of revision: May 2022.

HDM*: House dust mites

Your Symptom tracker

On a scale of 0-10, how severe are your symptoms? 0 = No symptoms, not disruptive to daily life; 5 = some symptoms, somewhat disruptive to daily life; 10 = severe symptoms, majorly disruptive to daily life				How many days of the week did you have to use other allergy medicines? (Make note of what you took)	Other notes and comments
Week commencing	Overall symptoms	Daytime symptoms	Night-time symptoms		

12 SQ-HDM SLIT-Tablet



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Call for reporting adverse events:

For more information about ACARIZAX® or in case of any safety concerns, please contact your doctor

To report any side effect(s), please contact:

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa/>

Or

The local representative of the Marketing Authorisation Holder in KSA:

Biologix, FZ Co,

Hibatullah Al Ghaffari Street-Sulimaniyah

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