

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ACARIZAX[®]?

ACARIZAX[®] contains the active ingredient standardised allergen extract from house dust mites, American house dust mite (*Dermatophagoides farinae*) and European house dust mite (*Dermatophagoides pteronyssinus*).

ACARIZAX[®] is for the treatment of house dust mite allergy that is characterised by rhinitis (sneezing, runny or itchy nose, nasal congestion) in adults and adolescents aged 12 years and above. It is also for the treatment of house dust mite related allergic asthma in adults.

For more information, see Section [1. Why am I using ACARIZAX[®]?](#) in the full CMI.

2. What should I know before I use ACARIZAX[®]?

Do not use if you have ever had an allergic reaction to ACARIZAX[®] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ACARIZAX[®]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ACARIZAX[®] and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ACARIZAX[®]?

The recommended dose of ACARIZAX[®] is one tablet per day.

More instructions can be found in Section [4. How do I use ACARIZAX[®]?](#) in the full CMI.

5. What should I know while using ACARIZAX[®]?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using ACARIZAX [®] .
Things you should not do	Do not stop using this medicine suddenly. Do not take the medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
Driving or using machines	This medicine is not expected to have any effect on your ability to drive or to use machines.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	Follow the instruction on the carton on how to take care of your medicine properly.

For more information, see Section [5. What should I know while using ACARIZAX[®]?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ACARIZAX[®] (a-kari-zaks)

Active ingredient(s): American house dust mite extract and European house dust mite extract

Consumer Medicine Information (CMI)

This leaflet provides important information about using ACARIZAX[®]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ACARIZAX[®].**

Where to find information in this leaflet:

- [1. Why am I using ACARIZAX[®]?](#)
- [2. What should I know before I use ACARIZAX[®]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ACARIZAX[®]?](#)
- [5. What should I know while using ACARIZAX[®]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ACARIZAX[®]?

ACARIZAX[®] contains the active ingredients, standardised allergen extract from house dust mites *Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*.

ACARIZAX[®] is for the treatment of house dust mite allergy that is characterised by rhinitis (sneezing, runny or itchy nose, nasal congestion) in adults and adolescents aged 12 years and above. It is also for the treatment of house dust mite related allergic asthma in adults.

2. What should I know before I use ACARIZAX[®]?

Warnings

Do not use ACARIZAX[®] if:

- you are allergic to **standardised allergen extract from house dust mites *Dermatophagoides farinae* and *Dermatophagoides pteronyssinus***, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have poor lung function (as assessed by your doctor)
- your asthma has worsened over the last 3 months (as assessed by your doctor)
- you have asthma as well as an ongoing airway infection such as a cold or chest infection on the day you are to take the first dose of ACARIZAX[®]. Your doctor may recommend delaying the start of your treatment until your cold or infection is better.
- you have an illness which affects your immune system or have cancer

- you have recently lost or had a tooth taken out had other forms of mouth surgery, have ulcers, wounds, or infections in the mouth (see [2. What should I know before I use ACARIZAX[®]?](#))
- Do not take the medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- are being treated for depression, asthma, Parkinson's disease or have a heart condition such as high blood pressure or an irregular heartbeat (see [3. What if I am taking other medicines?](#))
- have previously been treated for house dust mite allergy and had a severe allergic reaction, have recently lost or had a tooth taken out, had other forms of mouth surgery, are planning to have any form of mouth surgery, have ulcers, wounds or infections in the mouth. Your doctor may delay or stop your treatment until your condition has resolved.
- recovering or are in remission from an illness which affects your immune system
- have an inflamed oesophagus
- are taking steroids

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with ACARIZAX[®] and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect, or could be affected by ACARIZAX[®].

4. How do I use ACARIZAX®?

How much to take / use

- The recommended dose of ACARIZAX® is one tablet per day.
- Always follow the instructions given to you by your doctor or pharmacist.

When to take / use ACARIZAX®

ACARIZAX® should be taken at about the same time each day.

Taking it at the same time each day will help you get the best effect. It will also help you to remember when to take it.

Do not consume food and drink for 5 minutes after taking this medicine.

Food can interfere with the absorption of this medicine.

How to take ACARIZAX®

Make sure your hands are clean and dry before handling the medicine.

Follow the instructions below when taking ACARIZAX®:

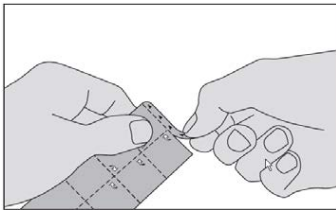


Figure 1: Tear off the strip marked with triangles at the top of the pack.

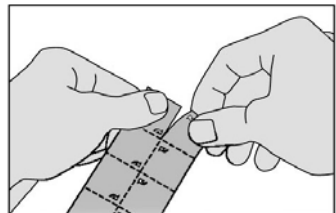


Figure 2: Tear a square off the pack along the dotted lines.

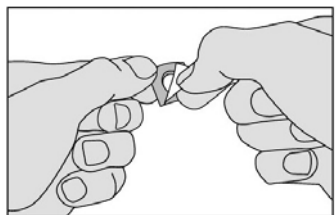


Figure 3: To remove the tablet, fold back the marked corner of the foil and then pull it off. Do not force the tablet through the foil - as it breaks easily.

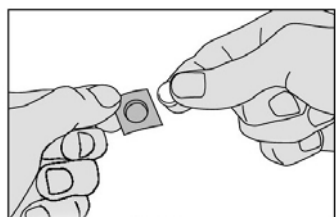


Figure 4: Remove the tablet carefully from the foil and place it under your tongue immediately.



Figure 5: Keep the tablet under your tongue until it has dissolved. Do not swallow for 1 minute. Do not eat or drink for at least 5 minutes after taking the tablet.

Your doctor should give you the first tablet under medical supervision and then monitor you for 30 minutes. This gives you the opportunity to discuss any possible side effects with your doctor ([6. Are there any side effects?](#)).

If you forget to use ACARIZAX®

If you forget to take a dose, take it later in the day.

Do not take a double dose to make up for the dose you missed.

If you have not taken ACARIZAX® for more than 7 days contact your doctor before taking ACARIZAX® again.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much ACARIZAX®

If you think that you have used too much ACARIZAX®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ACARIZAX®?

Things you should do

If you are about to be started on any new medicine, inform your doctor or pharmacist that you are taking ACARIZAX®.

Remind any doctor, dentist or pharmacist you visit that you are using ACARIZAX®.

If you become pregnant while taking this medicine, tell your doctor immediately.

You can expect some mild to moderate localised allergic reactions during your treatment. In most cases these reactions are only temporary. However, if you think these

are severe, talk to your doctor to see if you need any anti-allergic medicines such as antihistamines (see [6. Are there any side effects?](#)) **Tell your doctor if you feel the treatment is not helping your condition.**

Things you should not do

- Do not stop taking your medicine without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.
- Do not use ACARIZAX® to treat any other conditions unless your doctor tells you to.
- Do not give this medicine to anyone else even if they have the same conditions as you.
- Do not take this medicine if you are below 12 years of age.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ACARIZAX® affects you.

ACARIZAX® may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Keep it in a cool dry place where the temperature stays below 25°C.

Store the blister pack in the carton to protect the tablets from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Irritation of the throat • Dryness or redness of the mouth • Itching of the mouth, tongue, lips, eyes or ears • Inflammation of the nose and throat • Taste disturbance or loss of taste • Runny nose, blocked nose or sneezing 	<p>Tell your doctor or pharmacist if you notice any of these and they worry you:</p> <p>Speak to your doctor as soon as possible if you have any of these less serious side effects</p>
<ul style="list-style-type: none"> • Prickling sensation or numbness of the mouth or tongue • Itching, redness, watering of the eyes • Swelling of the mouth, throat, tongue or lips • Inflammation, discomfort or burning sensation in the mouth • Stomach pain or discomfort • Diarrhoea • Feeling sick (nausea) or vomiting • Pain when swallowing or difficulty in swallowing • Indigestion or heartburn • Hoarseness • Blistering of the mouth and mouth ulcers • Fast or irregular heartbeat • Sensation of something stuck in the throat • Tightness in the chest • Feeling tired or dizzy • Itching or redness of the skin, hives • Ear pain 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Worsening of existing asthma • Rapid swelling of face, mouth, throat or skin • Difficulties in swallowing or breathing • Voice changing • Start to feel faint • Feeling of fullness in the throat (like swelling) • Tightness in the throat. • Severe or persistent heartburn or difficulty in swallowing, as these symptoms could be signs of allergic inflammation of the oesophagus (eosinophilic oesophagitis) 	<p>Stop taking ACARIZAX®</p> <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects that you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ACARIZAX[®] contains

Active ingredient	Each ACARIZAX [®] tablet contains 12 SQ-HDM standardised allergen extract from the house dust mites <i>Dermatophagoides farinae</i> and <i>Dermatophagoides pteronyssinus</i> as the active ingredient
Other ingredients	The tablet also contains: <ul style="list-style-type: none">• gelatin (from fish)• mannitol• sodium hydroxide.
Potential allergens	This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What ACARIZAX[®] looks like

ACARIZAX[®] tablets are white to off-white with an imprint on one side. The tablets are individually packed in blister foils (AUST R 250392).

The following pack sizes are available: 10, 30 or 90 tablets. Not all pack sizes may be marketed.

Who distributes ACARIZAX[®]

Seqirus Pty Ltd
ABN: 26 160 735 035
63 Poplar Road, Parkville VIC 3052 Australia
Telephone: 1800 642 865
www.seqirus.com.au
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