

### **ACARIZAX® – sublingual allergy vaccination in tablet form**

The principle behind allergy vaccination is to supply your body with the substance (allergen) you are allergic to in controlled doses. The cause of the allergy is treated by helping the immune system to build tolerance to that particular allergen.

ACARIZAX® is a sublingual allergy vaccination in tablet form. It contains standardized allergen extract from the two species of house dust mites, which most often cause allergy. It treats allergy to house dust mites by slowly increasing your immune system's tolerance to the allergens from house dust mites. This leads to a decrease in symptoms. After having built tolerance to the allergen you will need to take less (or in some cases no) medication to relieve symptoms.

The tablet is indicated for adults 18-65 years (allergic rhinitis and allergic asthma) and adolescents 12-17 years (allergic rhinitis). It is important for you to follow your doctor's prescription carefully to make the treatment as effective as possible. **The treatment period is 3 years.**

### **Treatment with ACARIZAX®**

If you have any questions or are unsure about your treatment, it is important to talk to your doctor before you start taking the tablets. If you suffer from asthma, you should take your asthma medication throughout the treatment period as prescribed by your doctor.

### **ACARIZAX® is taken once a day**

You can start treatment with ACARIZAX® all year round. The treatment takes 3 years, one tablet daily. It is recommended that the first tablet is taken under medical supervision and that you stay at the doctor's office for 30 minutes after taking the tablet. This is to check that you are taking the tablet correctly and to enable a discussion and treatment of possible side effects.

### **Exercise caution when taking ACARIZAX® if:**

- You have acute severe oral inflammation or oral wounds. You must stop treatment until your mouth has healed.
- If the treatment with ACARIZAX® has been interrupted for more than 7 days, it is recommended to contact a physician before resuming the treatment.
- You have recently received an allergy vaccination in injection form and experienced severe side effects.
- Hypersensitivity to any of the excipients in the ACARIZAX® tablets.
- You suffer from asthma and the symptoms get worse when taking ACARIZAX®, you must contact your doctor.
- You suffer from asthma and have a respiratory infection, for example a cold. You must then stop treatment until the infection has passed.
- You suffer from asthma and have experienced a severe asthma exacerbation within the last 3 months when you start the treatment.

**You must not take ACARIZAX® if you have:**

- Uncontrolled or severe asthma
- Hypersensitivity to any substance in the tablet
- A disease that affects the immune system or cancer
- Inflammatory conditions in the mouth, e.g. sores, blisters or fungal infections

**ACARIZAX® and pregnancy:**

If you become pregnant during the treatment, contact your doctor, who will decide whether or not it is suitable for you to continue your treatment.

**How to take ACARIZAX®**

- Remove the tablet from the blister pack using dry fingers.
- Place the tablet under your tongue. Change between the right and left sides.
- The tablet dissolves in a few seconds.
- Do not swallow for a period of 1 minute after taking the tablet.
- Wait 5 minutes before eating or drinking.
- It is a good idea to rinse your mouth after 5 minutes.

If you forget to take a tablet, you can take it later on the same day. Never take a double dose to compensate for forgetting to take a tablet; continue as normal by taking one tablet per day.

- Avoid brushing your teeth before taking the tablet. Wait until afterwards.
- Avoid scratching or touching your eyes if you have just had a tablet in your hand.

**Follow the prescription from your doctor**

To reduce the allergic symptoms and to make sure the treatment has a lasting effect, your body needs to build up a tolerance to the substance you are allergic to, slowly and over a long period of time. It is important to remember to take one tablet every day, including days when you do not have any symptoms. To get the best results possible from the treatment, it is important to follow the doctor's prescription carefully.

**Remember the following when taking ACARIZAX®**

- Do not brush your teeth before taking the tablet, but afterwards.
- If you have a dry mouth, rinse your mouth out with water beforehand.
- Wash your hands after taking the tablet.
- Rinse your mouth 5 minutes after taking the tablet.
- You can take the tablet whenever you want during the day.
- Never take two tablets on the same day.
- You can take anti-histamines if you suffer from itching in your mouth when starting the treatment (you should always discuss this with your doctor before taking anti-histamine).
- If you suffer any allergy problems or symptoms, use your allergy medication when necessary.

**Possible side effects**

You can suffer from side effects at the beginning of your treatment. They normally last for minutes to hours when you take the ACARIZAX® tablet. For most people, the side effects will stop within 1-3 months of treatment. In rare cases the side effects can persist and be so severe that you have to stop the treatment.

- The most common side effect is itching in the mouth.
- You may also feel a tingling sensation, often under your tongue, immediately after taking the tablet.
- Other more unusual side effects are itching in your ears, sneezing, throat irritation, swelling in the mouth – normally under your tongue, stomach pains, vomiting and localised swelling of the lips.

**Contact your doctor if:**

- You unexpectedly suffer from more severe side effects, such as breathing or swallowing difficulties, rash, a change in your voice, dizziness or a lump in your throat.
- If you suffer from asthma and your asthma symptoms get worse.

In all of these cases, you should stop taking ACARIZAX® until the doctor makes a decision to the contrary.

## Questions and answers

### ***Why is it recommended that the first tablet is taken at the doctor's office?***

We recommend taking your first tablet at the doctor's surgery to check that you are taking the tablet correctly. It also gives you the chance to discuss any side effects with your doctor, and allows the doctor to treat them, if necessary.

### ***What are the most common side effects?***

The most common side effect of ACARIZAX® is itching in the mouth. Other possible side effects of ACARIZAX® include itching in your ears, sneezing, throat irritation and swelling in your mouth. Just as with the itching in the mouth, these are examples of allergic reactions which normally only last for a limited period when you start treatment. The side effects normally last from minutes to hours. In most cases, they will stop after 1-3 months of treatment. Your doctor should have given you detailed information about ACARIZAX®, but to be on the safe side, read the patient information leaflet in the pack before starting the treatment.

### ***What should I do if my asthma symptoms get worse?***

If you suffer from asthma and the symptoms get worse when being treated with ACARIZAX®, you must contact the doctor, who will assess whether your treatment should be stopped. It is important for you to take the asthma medication prescribed by your doctor.

### ***I have previously reacted strongly to an allergy vaccination against house dust mite allergy in injection form. Can I take ACARIZAX®?***

If you have previously reacted strongly to an allergy vaccination against house dust mites in injection form, you may be at a higher risk of similar reactions when being treated with ACARIZAX®. If this is the case, your doctor should make a full assessment before you start the treatment.

### ***What should I do if I forget to take a tablet?***

If you forget to take a tablet, you can take it later on the same day. Do not take a double dose to compensate for forgetting to take a tablet.

### ***Should I continue to take drugs to relieve my symptoms when taking ACARIZAX®?***

You should continue to take medication to relieve your symptoms when necessary.

### ***I have asthma. Should I continue to take my asthma medicine?***

Yes, you should continue to take the asthma medication prescribed by your doctor.