

## **GRAZAX® – allergy vaccination in tablet form**

The principle behind allergy vaccination is to supply the body with the substance you are allergic to in controlled doses. The cause of the allergy is treated by helping the body to build up a tolerance to that particular substance.

GRAZAX® is the first allergy vaccination that you can take in tablet form and contains grass pollen extract. It treats hay fever or the pollen allergen by slowly increasing your immune system's tolerance to the grass pollen. It leads to fewer symptoms, which means that you do not have to take as much medication to relieve symptoms.

The tablet can be taken by adults and children from five years old. 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.**

### **How to take GRAZAX®**

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

### **GRAZAX® is taken once a day**

You should start treatment with GRAZAX® at least 2 but preferably 4 months before the start of the grass pollen season to feel the effects from the very first summer. You have to take the treatment every day of the year for 3 years. You take the first tablet when you are at the doctor's surgery. This is to check that you are taking the tablet correctly. It also gives you the chance to discuss any side effects and allows the doctor to treat them, if necessary.

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

- You/your child has had a tooth extracted, has lost a tooth or has had any other kind of procedure in your mouth. You must stop treatment for seven days until your mouth has healed.
- You/your child has recently received an allergy vaccination in injection form and experienced severe side effects.
- You/your child has a severe fish allergy. GRAZAX® contains very small amounts of fish gelatine.
- If you/your child suffers from asthma and the symptoms get worse when taking GRAZAX®, you must contact your doctor.
- Your child suffers from asthma and has a respiratory infection, for example a cold. You must then stop treatment until the infection has passed.

**You must not take GRAZAX® 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

**GRAZAX® and pregnancy:**

If you fall pregnant during the treatment, contact your doctor, who will decide whether it is suitable for you to continue your treatment.

**How to take GRAZAX®**

- 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/your child has 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 slowly and over a long period of time to the substance you are allergic to. 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 GRAZAX®**

- 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.
- If you suffer any allergy problems in the spring or summer, 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 a few minutes to a few hours when you take the GRAZAX® tablet. For most people, the side effects will stop within a week 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/your child unexpectedly suffers 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 GRAZAX® until the doctor makes a decision to the contrary.

## Questions and answers

### ***Why do you recommend taking the first tablet 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 GRAZAX<sup>®</sup> is itching in the mouth. This is a temporary side effect that can start from the time you take the tablet and normally goes away by itself after a few minutes or an hour. After a week of treatment, this side effect goes away for most people. Other possible side effects of GRAZAX<sup>®</sup> 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 very limited period when you start treatment. Your doctor should have given you detailed information about GRAZAX<sup>®</sup>, 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 GRAZAX<sup>®</sup>, 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 grass pollen in injection form. Can I take GRAZAX<sup>®</sup>?***

If you have previously reacted strongly to an allergy vaccination against grass pollen in injection form, you may be at a higher risk of similar reactions when being treated with GRAZAX<sup>®</sup>. 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 stop taking GRAZAX<sup>®</sup> treatment during the summer?***

No, during the grass pollen season, you should continue the treatment as normal.

### ***Should I continue to take drugs to relieve my symptoms during the pollen season/summer?***

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.