

**Product information for GRAZAX®. Pharmaceutical form and composition:** GRAZAX® are oral lyophilisates (tablets) for specific immunotherapy that contain SQ standardised allergen extract of Timothy grass pollen (*Pheum pratense*) at a strength of 75,000 SQ-T per tablet. **Therapeutic indications:** Grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older) with clinically significant symptoms and a positive skin prick test and/or specific IgE test to grass pollen. **Posology and method of administration:** The daily dose is one tablet to be placed under the tongue. Avoid swallowing for about 1 minute. It is recommended that the first tablet is taken under medical supervision (20–30 minutes). Start treatment at least 2 months prior to the expected start of the grass pollen season and continue daily treatment throughout the year. It is recommended to continue treatment with GRAZAX® for a period of 3 years. Treatment should be initiated by physicians with experience in treatment of allergic diseases and the capability to treat allergic reactions. **Clinical efficacy:** In adults continuous daily treatment with GRAZAX® for at least 2 years results in a progressive immunomodulatory effect and in statistically significant effects on all scored individual rhinoconjunctivitis symptoms. No data in children beyond one grass pollen season is available. **Contraindications:** Hypersensitivity to excipients, malignancy or systemic diseases affecting the immune system, inflammatory conditions in the oral cavity with severe symptoms. Contraindicated in patients with uncontrolled or severe asthma. **Special warnings and precautions for use:** Oral surgery, shedding of deciduous tooth in children, asthma deterioration, children with concomitant asthma and experiencing an acute upper respiratory tract infection. **Interaction with other medicinal products and other forms of interaction:** Concomitant therapy with symptomatic antiallergic agents (e.g., antihistamines, corticosteroids and mast cell stabilisers) may increase the tolerance level of the patient to immunotherapy. No data on possible risks of simultaneous immunotherapy with other allergens. **Pregnancy and lactation:** No clinical experience. Animal studies do not indicate increased risk. Treatment should not be initiated during pregnancy. **Undesirable effects:** Primarily mild to moderate local allergic reactions are to be expected. In studies, 70% of patients reported undesirable effects in the first year of treatment. This number decreased markedly in the second year of continuous treatment. In the majority of patients the reactions start early in therapy, last from minutes to hours and tend to subside spontaneously within 1 to 7 days. If the patient experiences significant adverse events, antiallergic medication should be considered. In case of severe systemic reactions, angioedema, difficulty in swallowing, difficulty in breathing, changes in voice, feeling of fullness in the throat or asthma deterioration, a physician should be contacted immediately. In children and adolescents the adverse event profile is similar to that observed in adults, with a more frequent report of upper respiratory tract infection, abdominal pain, vomiting and swollen lip than in the adult population. **Overdose:** In adults doses up to 1,000,000 SQ-T have been tolerated. No data is available in children regarding exposure to doses above the recommended daily dose of 75,000 SQ-T. **Excipients:** Gelatin (fish source), mannitol, sodium hydroxide. **Shelf life:** 3 years. **Content of container:** Aluminium blister cards with 30, 90 or 100 tablets. **Marketing authorisation holder:** ALK-Abelló A/S, Bøge Alle 6–8, DK-2970 Hørsholm, Denmark. **Marketing authorisation number(S):** 21278. **Updated:** 24 November 2008

## Parental guide to



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# What is an allergy vaccination?

## Hay fever – a common condition

An increasing number of children in the Western world suffer from allergies such as hay fever. Today, as many as one in every five children in Europe suffers from allergic rhinitis and, in 50% of cases, the allergy is caused by a reaction to grass pollen (more commonly known as hay fever). People with hay fever experience cold-like symptoms such as runny or blocked nose, sneezing, itching, and/or watering and itching of the eyes during the grass pollen season.

Hay fever is a long-term (chronic) condition which, if left untreated, can impact upon your child's daily life, by impairing the concentration at school, by disrupting sleep, or by making socialising difficult or unpleasant. In addition, if your child already has one or more allergies, your child has a greater risk of developing new allergies and asthma.

Currently, there are three ways of 'treating' hay fever:

- avoiding the substance that causes the allergy
- using symptomatic medications such as antihistamines and nasal corticosteroids, to temporarily reduce symptoms
- undergoing allergy vaccination.

While the first two options may help reduce the symptoms of allergy temporarily, **allergy vaccination is the only treatment that targets the underlying cause of your child's allergy.**

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## Allergy vaccination

The principle behind allergy vaccination is to administer small amounts of the substance that your child is allergic to (the 'allergen') in order to help the body build up a natural tolerance. This means that even after stopping the treatment, the body may remain tolerant of the allergen in question and that hay fever symptoms will continue to be reduced. In addition to this, allergy vaccinations may prevent the development of asthma and new allergies.

Currently, the World Health Organisation (WHO) recommends a 3 to 5 year treatment schedule for allergy vaccination therapies. Compliance to this schedule is very important in order to build up a natural tolerance to the allergen in question and hence increase likelihood to maintain the control of symptoms once the treatment course is completed. The more compliant your child is the better treatment result your child will have.



## What is GRAZAX®?

**GRAZAX® is the first allergy vaccination in a tablet formulation.**

The tablet is suitable for children of 5 years of age and older. It contains a grass pollen extract, which helps your child to build up a natural tolerance to grass pollen. In this way, GRAZAX® is able to target the underlying cause of your child's hay fever, and not just the symptoms.



GRAZAX® will be prescribed to your child by a doctor with experience in the treatment of allergy in children. Before starting GRAZAX® treatment it is very important that you read the patient information leaflet inside the GRAZAX® packaging.

### Your child should not take GRAZAX® if:

- Your child is allergic (hypersensitive) to any of the excipients in the GRAZAX® tablet (other than the grass pollen extract).
- Your child has an illness which affects the immune system.
- Your child has severe asthma as assessed by your doctor (GRAZAX® can be used if your child has mild or moderate asthma).
- Your child has cancer.
- Your child has a severe inflammation in the mouth.

### Take special care with GRAZAX® if:

- Your child has recently shed a milk tooth or had a tooth taken out (or other forms of oral surgery). In this case treatment with GRAZAX® should be stopped for 7 days to allow the oral cavity to heal.
- You child has severe allergy to fish.
- Your child has asthma and develops an upper respiratory infection (common cold). In this case treatment should be temporarily discontinued until the infection has resolved.
- Your child has previously had injection grass allergy vaccination and experienced severe allergic reactions, since there may be an increased risk of experiencing a similar reaction with GRAZAX®.

If your child has any of the above (or if you are unsure) it is important that you talk to your child's doctor before they start taking GRAZAX®, or while GRAZAX® is being used.

### GRAZAX® should be taken once-daily.

To get the best effect, your child should start taking GRAZAX® at least 2–4 months prior to the expected start of the grass pollen season, and continue treatment all year round. It is recommended to continue treatment for 3 years.

The tablet should be taken out from the blister card with dry fingers, and it is important that the tablet is placed under the tongue of the child, where it will dissolve within seconds. Your child should avoid swallowing for 1 minute, and avoid food and drink for 5 minutes after taking the tablet.

**1.** The tablet should be taken from the blister card with dry fingers

**2.** ...placed under the tongue

**3.** ...where it will dissolve within seconds

**4.** Swallowing should be avoided for 1 minute after taking the tablet.  
Food and drink should be avoided for 5 minutes after taking the tablet.

In order to gain maximum benefit from treatment with GRAZAX<sup>®</sup>, it is important that a tablet is taken, as prescribed by the doctor, every single day. Should your child forget to take a tablet, let your child take it later in the day if possible, but otherwise just continue with normal once-daily routine. Do not let your child take a double dose to make up for a forgotten tablet.

**It is important that the first GRAZAX<sup>®</sup> tablet be taken at the doctor's clinic. This is to ensure that the tablet is taken correctly and to provide you and your child with the opportunity to discuss any side effects with the doctor.**

If your child experiences side effects that are worsening on a daily basis, please contact your child's doctor and discuss if treatment of the side effects with symptomatic therapy should be considered (such as with antihistamines). In rare cases the local side effect may persist despite addition of symptomatic medications and/or be of a severity that may require the doctor to consider stopping GRAZAX<sup>®</sup> therapy.

## Possible side effects

The most common side effect of GRAZAX<sup>®</sup> treatment is itching of the mouth (a tingling sensation most often experienced under the tongue). This is a temporary effect that starts right after intake of the tablet, and that normally only lasts for a period of minutes to hours. However, after only one week of treatment, the majority of patients no longer experience itching of the mouth.

Other possible side effects with GRAZAX<sup>®</sup> treatment include itching of the ears, sneezing, throat irritation, swelling of the mouth (most often the area under the tongue), abdominal pain, vomiting, and localised swelling of the lip. As with itching of the mouth, these side effects mainly occur within the first week of treatment, are mild-to-moderate in severity, and are short-lived.

In the unlikely event that your child experiences a more severe side effect with GRAZAX<sup>®</sup> treatment, such as difficulty swallowing, difficulty breathing, rash, a change in voice, dizziness, or a feeling of fullness in the throat, then you should contact a doctor immediately. If your child has asthma and the symptoms worsen while taking GRAZAX<sup>®</sup>, you should also consult a doctor. In both these cases, the child should stop taking GRAZAX<sup>®</sup> until advised otherwise by the doctor.

## Compliance is important

In order to decrease your child's hay fever symptoms and to maintain the control of symptoms once the treatment is stopped, the body needs to build up a tolerance to the allergen to which your child is allergic. Therefore, it is important that your child remembers to take GRAZAX<sup>®</sup>, as prescribed by your doctor, both when your child has symptoms as well as when your child is not bothered by symptoms. Remember that the more compliant your child is the better treatment result he/she will have.

## Frequently asked questions

### **1. Why is it advised that my child take the first GRAZAX® tablet at the doctor's clinic?**

It is recommended that the first GRAZAX® tablet be taken at the doctor's clinic. This is to ensure that the tablet is taken correctly and to provide you and your child with the opportunity to discuss any side effects that may be seen with the doctor as well as to take any appropriate action if required.

### **2. What to do in case of tooth shedding?**

In case of shedding of a deciduous tooth (milk tooth) your child should stop the treatment for seven days to allow healing.

### **3. What should I do if my child experiences an upper respiratory infection?**

If your child has asthma and experiences an upper respiratory infection (common cold) GRAZAX® treatment should be temporarily discontinued until the infection has resolved. If your child does not have asthma he/she can continue to take GRAZAX® as before.

### **4. What should I do if my child has increasing asthma attacks (asthma exacerbations)?**

If your child has asthma and the asthma symptoms worsen while taking GRAZAX®, you should consult your child's doctor in order to evaluate if GRAZAX® treatment should be discontinued. It is important that your child continues to take their asthma medication as instructed by their doctor (your child should follow his/her asthma "Action Plan").

### **5. My child has a fish allergy, is there anything I have to worry about when taking GRAZAX®?**

The GRAZAX® tablet contains very small amounts of fish protein; therefore if your child has a severe allergy to fish this should be discussed with your doctor before starting therapy.

### **6. My child did not previously tolerate injection grass allergy vaccination, can they take GRAZAX®?**

If your child has previously had a severe reaction to injection grass allergy vaccination, the risk of experiencing a similar reaction with GRAZAX® may be increased. Therefore, the use of GRAZAX® in these patients should be carefully considered by the doctor.

### **7. What should I do if my child forgets to take their GRAZAX®?**

If your child has forgotten to take their GRAZAX® it can be taken later the same day. Do not let your child take a double dose on any one day to make up for a forgotten tablet.

### **8. What should I do if my child takes more GRAZAX® than they should?**

If your child has taken too many GRAZAX® your child may experience allergic symptoms including local symptoms from mouth and throat. If your child experiences severe symptoms, you should immediately contact a doctor or a hospital.

## Further information

To find out more information about allergy and asthma, you may wish to contact one of the following national organisations:

**[Include specific address/contact details of relevant national allergy and asthma organisations, pollen flight calendars]**

For more information about GRAZAX®, please visit [www.GRAZAX.com](http://www.GRAZAX.com).