

PACKAGE LEAFLET: INFORMATION FOR THE USER

Grazax 75,000 SQ-T oral lyophilisate

Standardised allergen extract of grass pollen from Timothy (*Phleum pratense*)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again
- If you have further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1. What Grazax is and what it is used for
2. Before you take Grazax
3. How to take Grazax
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1. What Grazax is and what it is used for

Grazax contains an allergen extract of grass pollen. Grazax is used to treat rhinitis and conjunctivitis caused by grass pollen in adults and children (5 years or older). Grazax modifies the allergic disease by increasing immunological tolerance towards grass pollen. The effect is sustained after you have completed treatment

Children are carefully selected for treatment by doctors experienced in the treatment of allergic diseases in children.

The doctor will evaluate your allergic symptoms and make a skin prick test or take a blood sample in order to decide if Grazax should be used for treatment.

You are advised to take the first oral lyophilisate under medical supervision. This is a precaution in order to evaluate each patient's sensitivity to the treatment. This gives you the possibility of discussing possible side effects with the doctor.

Grazax is prescribed by doctors with experience in treatment of allergy.

2. Before you take Grazax

Do not take Grazax if:

- You are allergic (hypersensitive) to any of the excipients in the oral lyophilisate
- You have an illness which affects the immune system
- You have severe asthma (as assessed by your doctor)
- You have cancer
- You have a mouth inflammation which is severe

Take special care with Grazax if:

- You have recently had a tooth taken out or other forms of oral surgery. Treatment with Grazax should in this case be stopped for 7 days to allow your oral cavity to heal
- You have severe allergy to fish
- You previously have had an allergic reaction in connection with injection of allergen extract of grass pollen

Use in children

- Shedding of a deciduous (milk) tooth. Treatment with Grazax should in this case be stopped for 7 days to allow the oral cavity to heal
- In children with asthma experiencing an acute upper respiratory tract infection Grazax treatment should be temporarily discontinued until the infection has resolved.

If any of the above applies to you, talk to your doctor before taking Grazax.

There is no experience with Grazax in the elderly (65 years and older).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you are taking other medicines for your allergy symptoms such as antihistamines or corticosteroids your doctor should evaluate the use of such medicines.

Taking Grazax with food and drink

Food and drink should not be taken for 5 minutes after taking this oral lyophilisate.

Pregnancy and breast-feeding

At present there is no experience for the use of Grazax during pregnancy. Treatment with Grazax should not be initiated during pregnancy. If you become pregnant during treatment, speak to your doctor about whether it is appropriate for you to continue the treatment.

At present there is no experience for the use of Grazax during breast-feeding. No effects on the breastfed infants are anticipated.

Driving and using machines

You alone are responsible for the judgement of your ability to drive or perform precision work. Effects or side effects from medicine may influence this ability. A description of these effects is available in other sections of this leaflet. Thus, for guidance read all the information in this leaflet.

You should check with your doctor or pharmacist if you are not sure.

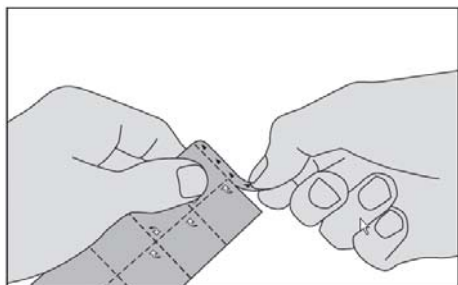
Treatment with Grazax has no or negligible influence on the ability to drive or use machines.

3. How to take Grazax

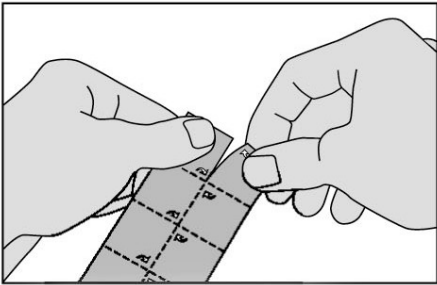
Always take Grazax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one oral lyophilisate daily. To get the best effect start taking the oral lyophilisates 4 months prior to the expected start of the grass pollen season and continue all year round. It is recommended to continue treatment for 3 years.

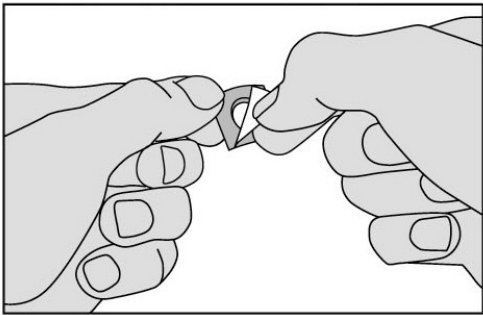
Grazax is an oral lyophilisate. Make sure your hands are dry before handling the oral lyophilisates. Take the oral lyophilisates like this:



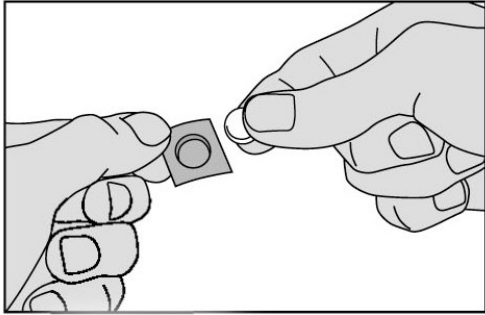
1. Tear off the strip marked with triangles at the top of the oral lyophilisate pack.



2. Tear a square off the oral lyophilisate pack along the perforated lines



3. Do not force the oral lyophilisate through the foil. It may damage the oral lyophilisate as it easily breaks. Instead, fold back the marked corner of the foil and then pull it off.



4. Remove the oral lyophilisate carefully from the foil and take the oral lyophilisate immediately



5. Place the oral lyophilisate under the tongue. Allow it to remain there for a few seconds until it has dissolved. Do not swallow during the first minute. Do not eat or drink for at least 5 minutes.

If you take more Grazax than you should

If you have taken too many Grazax oral lyophilisates you may experience allergic symptoms including local symptoms from mouth and throat. If you experience severe symptoms, immediately contact a doctor or a hospital.

If you forget to take Grazax

If you have forgotten to take an oral lyophilisate, take it later in the day. Do not take a double dose on any one day to make up for a forgotten oral lyophilisate.

If you stop taking Grazax

If you do not take this medicine as prescribed, you may not have an effect of the treatment. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Grazax can cause side effects, although not everybody gets them.

The side effects may be an allergic response to the allergen you are being treated with. In most cases the side effects last from minutes to hours after taking the oral lyophilisate and settles down within one week of starting the treatment.

Very common (affecting more than 1 in 10 people): Itching in the mouth and ears, irritating sensation in the throat, sneezing and swelling in the mouth.

Common (affecting more than 1 in 100 but less than 1 in 10 people): Itchy eyes, inflammation in the eyes, stuffy or runny nose. Swelling, prickling, numbness, blistering, or other discomforts of mouth and tongue. Swollen lips. Tiredness, Headache. Itching. Nettle rash. A feeling of swelling or tightness in the throat, coughing, asthma. Gastrointestinal problems such as stomach pain, feeling sick and heartburn. Inflammation in the throat.

Uncommon (affecting more than 1 in 1000 but less than 1 in 100 people): Lip blister, mouth ulceration, pain in mouth and gullet, inflammation in the mouth, dryness of mouth and throat, affection of the tongue, salivary gland disorders, difficulty in swallowing, vomiting, diarrhoea. Feeling of swollenness in the throat, discomfort at breathing, short of breath, wheezing breath, hoarseness. Inflammation of the nose and throat. Infection of the upper respiratory tract. Dizziness. Lymph node swelling. Lowered blood pressure. Allergic reaction. Chest discomfort, chest pain, chest tightness. Feeling hot, feeling of discomfort, fever. Sensation of foreign body in the throat. Eye swelling.

Rare (affecting more than 1 in 10000 but less than 1 in 1000 people): Sensation of rapid, forceful or irregular beating of the heart.

Stop the intake of Grazax and contact your doctor or hospital immediately if you experience any of the following symptoms:

- Swelling of the face, mouth or throat
- Difficulties in swallowing
- Rash
- Difficulties in breathing
- Voice changes
- Worsening of existing asthma

Upper respiratory tract infection, abdominal pain, and vomiting are reported more frequently in children than in adults.

If you have troublesome side effects you should contact your physician who will determine the anti-allergy medicines you may require, such as antihistamines.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Grazax

Keep out of the reach and sight of children.

Do not use Grazax after the expiry date stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Grazax contains

The active substance is SQ standardised allergen extract of grass pollen from timothy (*Phleum pratense*). The activity per oral lyophilisate is expressed using the unit SQ-T*. The activity of one oral lyophilisate is 75,000 SQ-T.

* (Standardised Quality units Tablet (SQ-T))

The other ingredients are gelatine (fish source), mannitol and sodium hydroxide.

What Grazax looks like and contents of the pack

White to off-white circular oral lyophilisate marked with a debossed image on one side.

Aluminium blister cards with removable aluminium foil in an outer box of carton. Following packages are available: 30, 90 or 100 oral lyophilisates.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

ALK-Abelló A/S
Bøge Allé 6-8
DK-2970 Hørsholm
Denmark

This leaflet was last approved in 25 September 2009