

PACKAGE LEAFLET: INFORMATION FOR THE USER

GRAZAX® 75,000 SQ-T sublingual lyophilisate

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

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Grazax is and what it is used for
2. What you need to know before you take Grazax
3. How to take Grazax
4. Possible side effects
5. How to store Grazax
6. Contents of the pack and other information

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.

Children are 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 sublingual 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. What you need to know before you take Grazax

Do not take Grazax if:

- You are allergic (hypersensitive) to any of the excipients in this medicine (listed in section 6)
- 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

Warnings and precautions

Talk to your doctor before taking 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
- You have asthma and are experiencing an acute upper respiratory tract infection. Grazax treatment should be temporarily discontinued until the infection has resolved.

Some side effects can be severe and need immediate medical care. Please see section 4 for symptoms.

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

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).

Other medicines and Grazax

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.

Grazax with food and drink

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

Pregnancy, breast-feeding and fertility

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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much Grazax to take

- The recommended dose is one sublingual lyophilisate daily.

How to take Grazax

- To get the best effect start taking the medicine 4 months before the expected start of the grass pollen season. It is recommended to continue Grazax treatment for 3 years.

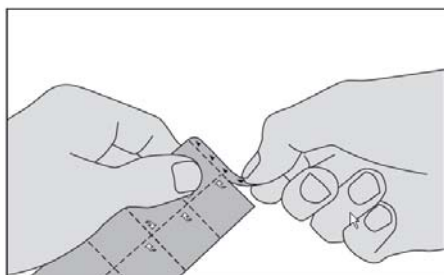
The first dose of Grazax should be taken at the doctor's office.

- This is because you should stay under medical observation for about half an hour after taking the first dose.
- This is a precaution to check your sensitivity to the medicine.
- This will also give you the chance to discuss with the doctor, any possible side effects you may have.

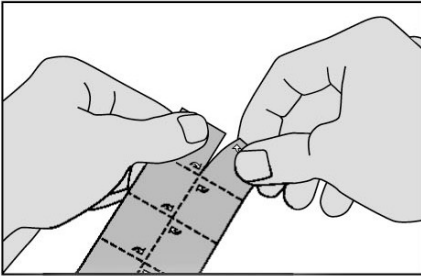
Keep taking Grazax every day - even if it takes some time before your allergy improves. If your allergy symptoms do not get better during the first grass pollen season, then you should see your doctor to discuss the continuation of the treatment.

Make sure your hands are dry before handling the medicine.

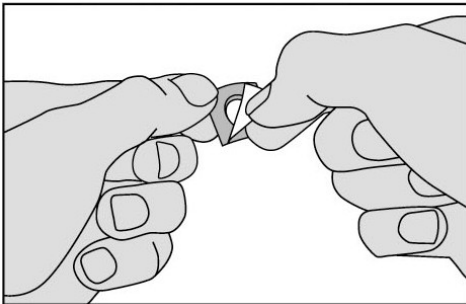
Take the sublingual lyophilisates like this:



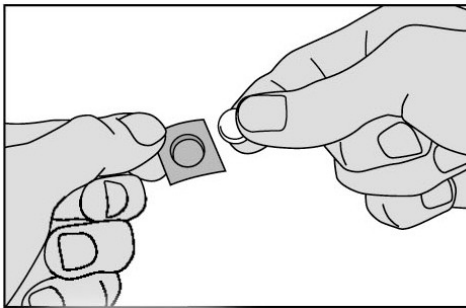
1. Tear off the strip marked with triangles at the top of the pack.



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



3. Fold back the marked corner of the foil and then pull it off. Do not force the medicine through the foil- as it breaks easily.



4. Remove the medicine carefully from the foil and place it under your tongue straight away.



5. Keep the medicine 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 medicine.

If you take more Grazax than you should

If you have taken too many Grazax sublingual 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 a sublingual lyophilisate, take it later in the day. Do not take a double dose on any one day to make up for a forgotten sublingual 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, this medicine 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 sublingual lyophilisate and settles down within one week of starting the treatment.

Serious side effects:

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

- Rapid swelling of face, mouth or throat
- Difficulties in swallowing

- Difficulties in breathing
- Hives
- Voice changes
- Worsening of existing asthma
- Severe discomfort

If you experience persisting heartburn you should contact your physician

Possible other side effects:

Very common (may affect more than 1 in 10 people):

- Swelling of mouth
- Mouth or ear itching
- Irritating sensation in the throat

Common (may affect up to 1 in 10 people):

- Prickling sensation or numbness of the mouth
- Eye, lip or nose itching
- Eye or mouth inflammation
- Shortness of breath, cough or sneezing
- Dry throat
- Runny nose
- Swelling of eyes or lips
- Mouth ulcers
- Blistering pain or discomfort of mouth or throat
- Stomach pain, diarrhoea, feeling sick, vomiting
- Heartburn
- Itching rash or nettle rash
- Tiredness
- Chest discomfort
- Tightness of throat
- Mouth redness
- Difficulty in swallowing

Uncommon (may affect up to 1 in 100 people):

- Sensation of rapid, forceful or irregular beating of the heart

- Altered taste
- Eye redness or irritation
- Ear pain or discomfort
- Numbness in the throat, painful swallowing
- Tonsil enlargement
- Serious allergic reaction
- Dry mouth
- Lip blister, lip inflammation, lip ulcers
- Salivary gland enlargement or hypersecretion
- Inflammation of the stomach, regurgitation
- Sensation of foreign body in the throat
- Skin redness
- Swelling of face
- Inflammation of the tongue
- Allergic reaction
- Prickling sensation of the skin
- Stomach discomfort
- Swelling of throat
- Tear flow
- Hoarseness
- Red throat
- Blisters in the mouth

Rare (may affect up to 1 in 1,000 people):

- Lower airways constriction
- Ear swelling

Eye irritation, red throat, blisters in the mouth, ear pain and ear swelling 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.

Reporting of side effects

In UK: If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for “MHRA Yellow Card” in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

In Ireland: If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the HPRA via HPRA Pharmacovigilance; Website www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Grazax

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Grazax contains

The active substance is SQ standardised allergen extract of grass pollen from timothy (*Phleum pratense*). The activity per sublingual lyophilisate is expressed using the unit SQ-T*. The activity of one sublingual 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 sublingual lyophilisate marked with a debossed image on one side.

Aluminium blister cards with removable aluminium foil in an outer box of carton. Each blister card contains 10 sublingual lyophilisates. Following packages are available: 30 (3x10), 90 (9x10) or 100 (10x10) sublingual 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

Manufacturer

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