

Package leaflet: information for the user

GRAZAX®, lyophilisate for oral use 75,000 SQ-T
Standardized allergen extract of Timothy grass pollen (*Phleum pratense*)

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is GRAZAX and what is it used for?

GRAZAX contains an allergen extract of grass pollen. GRAZAX is used by adults and children (from 5 years) for the treatment of inflammation of the nasal mucosa (rhinitis) and conjunctivitis caused by grass pollen.

GRAZAX has a beneficial effect on the natural course of the allergic condition by increasing immunological tolerance to grass pollen.

Children are selected for treatment by doctors experienced in treating allergic conditions in children.

The doctor will assess the allergic symptoms and perform a skin prick test or take a blood sample to decide on treatment with GRAZAX.

You are advised to take the first GRAZAX tablet under medical supervision. This is a precautionary measure to observe the patient's reaction to the treatment. This gives you the opportunity to discuss possible side effects with your doctor.

GRAZAX is prescribed by doctors who have experience in treating allergic conditions.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- if you are allergic to any of the excipients in this medicine. These substances can be found in section 6.
- if you have a condition that affects the functioning of the immune system.
- if you have severe asthma (diagnosed by the doctor)
- if you have cancer

- if you have a severe inflammation in the mouth

When should you be extra careful with this medicine?

Contact your doctor before taking this medicine

- if you have recently had a tooth removed or if you have had another surgical procedure in the mouth. In these cases, treatment with GRAZAX should be stopped for a period of 7 days to allow the mouth to heal.
- if you have a severe fish allergy.
- if you have had an allergic reaction in the past to an injection with a grass pollen allergen extract
- if you have asthma and suddenly get an upper respiratory tract infection. Treatment with Grazax should be temporarily stopped until the infection has cleared.

Some side effects can be serious and require immediate medical attention. See chapter 4 for these complaints.

Children

- Changing of the milk teeth. In this case, the GRAZAX treatment should be stopped for a period of 7 days to allow the oral cavity to heal.

If any of the above situations apply to you, contact your doctor before taking GRAZAX. There is no data on the use of GRAZAX by the elderly (from 65 years).

Are you using any other medicines?

Tell your doctor or pharmacist if you are using or have recently used other medicines. This also applies to medicines that you can obtain without a prescription. If you are using other medicines for your allergic symptoms, such as antihistamines or corticosteroids, you should discuss this with your doctor.

What should you pay attention to with food and drink?

After taking GRAZAX, you must wait at least 5 minutes before eating or drinking.

Pregnancy, breastfeeding, and fertility

At this moment, there is no experience with the use of GRAZAX during pregnancy. Treatment with GRAZAX should not be started in pregnant women. If pregnancy occurs during treatment, ask your doctor if you can continue the treatment.

At this moment, there is no experience with the use of GRAZAX in women who are breastfeeding. No effects are expected in breastfed children.

Driving and using machines

You are responsible for assessing whether you are able to drive or perform precise work. The effects or side effects of the medicine may influence these abilities. A description of these effects is provided later in this leaflet. Read the entire leaflet to be well informed. Consult your doctor or pharmacist if in doubt.

Treatment with GRAZAX has no or little influence on the ability to drive and operate machines.

3. How do you take this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

How much of this medicine do you use?

- The recommended dosage is one lyophilisate (orodispersible tablet) orally per day.

How do you use this medicine?

- To achieve the best effect, you should start taking GRAZAX at least 4 months before the start of the grass pollen season. It is recommended to continue treatment with GRAZAX for 3 years.

The first dose of this medicine must be taken in the doctor's office.

- This is because you need to remain under medical supervision in the doctor's office for about half an hour after taking the first dose.
- This is a precaution to monitor your sensitivity to the medicine.
- This also gives you the opportunity to discuss any side effects you may experience with the doctor.

Continue taking this medication every day, even if it takes some time for your allergy to improve. Inform your doctor if your allergy symptoms do not improve during the first grass pollen season. Your doctor will discuss with you whether to continue the treatment.

Make sure your hands are dry before removing the medication from the packaging.

Remove the medication from the packaging as follows:

1. Tear off the edge with the triangles from the top of the blister pack.
2. Tear off a square from the blister pack along the dotted lines.
3. Fold the marked corner of the cover foil and pull off the foil. Do not push the medication through the foil, as the melt-in-the-mouth tablet breaks easily.
4. Carefully remove the medication from the foil and place it directly under the tongue.
5. Hold the medication under the tongue until the melt-in-the-mouth tablet is dissolved.
 - Do not swallow for 1 minute after placing this medication under the tongue.
 - Do not eat or drink for at least 5 minutes after placing this medication under the tongue.

Have you taken too much of this medication?

If you have taken too much GRAZAX, you may experience allergic symptoms, including local symptoms in the mouth and throat. If you experience severe symptoms, contact your doctor or hospital immediately.

Have you forgotten to take this medication?

If you have forgotten to take GRAZAX, take it later in the day. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medication

If you do not take this medication as prescribed, the treatment may not be effective. Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. The side effects may be an allergic reaction to the allergen you are being treated for. In most cases, the side effects last minutes to hours after taking GRAZAX and subside within a week after starting the treatment.

Serious side effects:

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

- Sudden swelling of the face, mouth, or throat
- Difficulty swallowing
- Difficulty breathing
- Hives (rash with intense itching)
- Change in voice
- Worsening of existing asthma
- Severe discomfort

If you experience persistent heartburn, contact your doctor.

Possible other side effects:

Very common (occur in more than 1 in 10 users):

- Swelling in the mouth
- Itching in mouth or ear
- Irritating feeling in the throat

Common (occur in less than 1 in 10 users):

- Tingling or numbness of the mouth
- Itchy eyes, lips, or nose
- Eye inflammation, inflammation in the mouth
- Shortness of breath, coughing, or sneezing
- Dry throat
- Runny nose
- Swelling of eyes or lips
- Mouth ulcers
- Blister pain or discomfort in the mouth or throat
- Stomach pain, diarrhea, feeling sick, vomiting

- Heartburn
- Itching, rash or hives (rash on the skin with pink bumps and severe itching)
- Fatigue
- Unpleasant feeling in the chest
- Tight feeling in the throat
- Redness of the mouth
- Difficulty swallowing

Sometimes (occur in less than 1 in 100 users):

- Feeling of rapid, strong or irregular heartbeat
- Altered taste
- Redness or irritation of the eyes
- Ear pain or unpleasant feeling in the ear
- Numb throat, pain with swallowing
- Swelling of the tonsils
- Severe allergic reaction
- Dry mouth
- Blisters on the lip, lip inflammation, lip ulcers.
- Salivary gland enlargement or excessive saliva production
- Stomach inflammation, regurgitation of stomach contents
- Feeling something strange in the throat
- Red skin
- Swelling of the face.
- Inflammation of the tongue
- Allergic reaction
- Tingling sensation of the skin
- Stomach complaints
- Swelling of the throat
- Watery eyes
- Hoarseness
- Red throat
- Blisters in the mouth

Rare (occur in less than 1 in 1,000 users):

- Narrowing of the lower airways.
- Swelling of the ear

Eye irritation, red throat, blisters in the mouth, ear pain, and swelling of the ear are reported more often in children than in adults.

If you experience unpleasant side effects, you can contact your doctor. They can advise which antiallergic medications such as antihistamines you can use.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands

Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the blister and the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

This medicine does not require any special storage conditions.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is SQ standardized allergen extract of Timothy grass pollen (*Phleum pratense*). The activity per oral lyophilisate (a type of melt-in-the-mouth tablet) is expressed in the unit SQ-T*. The activity of one oral lyophilisate is 75,000 SQ-T.

* (standardized quality unit tablet (SQ-T)).

The other substances in this medicine are gelatin (derived from fish), mannitol, and sodium hydroxide.

What does GRAZAX look like and what is in a package?

Round and white to off-white oral lyophilisate with an embossed image on one side.

Aluminum blister strip with aluminum cover foil in a cardboard box. Each blister strip contains 10 oral lyophilisates.

Package size: 100 (10x10) oral lyophilisates.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Registration holder/repacker:

Originalis B.V. Diamantweg 4
1812 RC Alkmaar

Manufacturer

ALK-Abelló S.A. Miguel Fleita 19
28037 Madrid Spain

Grazax[®] is a registered trademark of ALK-Abelló A/S

Registered in the register under:
RVG 127204/33788 (Czech Republic)

This medicine is registered in EEA member states under the following names:

Czech Republic GRAZAX

This leaflet was last approved in September 2020.

Transtoyou