

Patient information leaflet

Sublingual Immunotherapy (SLIT) for Timothy Grass Pollen with GRAZAX: General Information

What is sublingual immunotherapy?

There are several ways of re-training the immune system to tolerate a substance the individual is allergic to (desensitisation). For grass pollens, which are inhaled allergens, the immune system can be desensitised by either administering grass pollen extract under the skin (subcutaneous immunotherapy, SCIT) or under the tongue (sublingual immunotherapy, SLIT). The sublingual (under the tongue) route is convenient (as it does not involve injections) and very safe, provided the instructions about product administration are followed correctly.

What is GRAZAX?

GRAZAX is a sublingual (under the tongue) immunotherapy treatment suitable for patients with severe hay fever symptoms caused by Timothy grass pollen allergy. It does not treat allergies caused by other types of grass pollens or tree pollens. GRAZAX is a dispersible tablet that contains a measured amount of Timothy grass pollen extract.

Can anybody take Grazax?

Grazax cannot be given to children younger than 5 years and to individuals with certain medical conditions or who are on certain medications (severe asthma, fish allergy, beta blocker medications, to name a few). Your allergist will make an individual assessment and decide if Grazax can be considered as a treatment option. Grazax is unlikely to benefit individuals with milder hay fever symptoms and should only be considered if hay fever symptoms are severe and the usual hay fever medications are not working despite regular use.

What are the benefits of taking GRAZAX?

The treatment aims to re-train the immune system of the allergic individual to tolerate Timothy grass pollen better. At the end of the treatment period the patient can expect around 40% reduction in symptoms caused by Timothy grass pollen allergy and 40% reduction in the regular medications taken to relieve these symptoms (e.g. antihistamines, nasal sprays etc). The treatment is not a complete cure, as it does not hold the promise to eliminate the Timothy grass pollen allergy altogether, but helps tolerate the individual to a point where the allergy symptoms are much milder. The benefit of the treatment is sustained for a number of years after cessation of immunotherapy. In individuals who do not already have asthma, immunotherapy also reduces the risk of future asthma. In those who have seasonal asthma due to Timothy grass allergy, the treatment is expected to reduce asthma symptoms and asthma medication use.

How is GRAZAX taken?

The very first dose is given in hospital, to ensure it is well tolerated. During this visit you will be given instructions about how to continue administering the medication at home.

The tablet should be taken every day at a fixed time. The tablet is simply placed under the tongue with clean dry hands. It melts almost immediately, but the patient is instructed not to swallow for 1-2 min so that the extract is absorbed via the lining of the mouth. After 1-2 minutes the patient can swallow as normal.

Can GRAZAX treatment be started at any time?

No. GRAZAX should be started 8 weeks prior to the expected start of the grass pollen season. We usually initiate GRAZAX treatment in January or February.

How long is GRAZAX taken for?

To get the maximum benefit from this treatment, GRAZAX should be taken every day for 3 years. The dose remains the same for the whole duration of treatment (1 tablet a day).

There are certain conditions, such as feverish illness and dental extractions, where the treatment should be discontinued for a short time until the patient is recovered, after which the treatment should be re-started promptly. You/your child will be instructed about these exceptional conditions and when and how to re-start treatment.

What are the possible side effects of GRAZAX?

The most common side effect of the treatment is tingling or itching sensation under the tongue, in the mouth, throat or ears. This tends to happen immediately after the tablet is administered and usually lasts for no more than 10-15 min. Itch and tingling can be managed by taking an antihistamine 30min before taking the GRAZAX tablet. These complaints usually subside once the body gets used to the treatment, within 2-3 weeks. However, if they persist you should discuss this with your allergist.

Other rarer side effects include headaches, tiredness, swelling of the tongue or lips, itchy hives on skin, eczema flare, sneezing, runny or blocked nose and watery itchy eyes. You should take antihistamine if these complaints occur and inform your allergist. Very rarely the patient may experience more severe symptoms such as difficulty swallowing, hoarse voice, feeling of swollen throat, difficulty breathing, wheeze or feeling unwell and dizzy. These symptoms would be exceptionally unlikely to occur if the medication has been tolerated well initially and is taken in the correct way.

How long will the beneficial effect of GRAZAX last?

This varies from one individual to another. In general, the effect of this treatment is expected to last for at least 5 years after initiation and up to 10 years.

Should I stop taking my other hay fever medications if I am on GRAZAX?

No. For the first hay fever season after you have started GRAZAX you must remain on the same regular hay fever medications you were taking before. This means you must start your daily eye drops, antihistamines and steroid nasal spray at the end of March as you have done before. Your doctor will guide you about how to reduce your regular hay fever medications at follow up in clinic visits, depending on the severity of your symptoms.

Sublingual Immunotherapy (SLIT) for Timothy Grass Pollen with GRAZAX -Specific information about treatment

How to take Grazax

- NEVER take more than one tablet per day.
- Do not exercise for 1 hour before administration.
- Take the medication at a fixed time every day, ideally in the morning.
- Ensure patient's mouth is clean of food, rinse mouth if necessary.
- Remind/remember the need to hold the tablet under the tongue for 1-2 min before swallowing.
- Ensure hands are clean and DRY.
- Tear off the strip marked with triangles at the top of the pack.
- Tear a square off the pack along the perforated lines.
- DO NOT force the tablet through the foil. It may damage the tablet as it easily breaks. Instead, fold back the marked corner of the foil and then pull it off.
- Remove the tablet carefully from the foil with dry hands.
- Take tablet immediately by opening the mouth, lifting tongue up and gently placing the tablet under the tongue.
- Do not swallow for 1-2 min to allow the extract to be absorbed through the lining of the mouth under the tongue.
- Do not eat or drink anything for the next 5-10 minutes after administration.
- Do not exercise for 1 hour after administration.
- The extract in the tablet needs to be absorbed to the body through the lining of the mouth under the tongue. Therefore, NEVER chew the tablet and NEVER swallow the tablet directly.

When should GRAZAX be stopped?

GRAZAX should be stopped if any of the following happens:

1. Asthma attack
2. Infection
3. Fever
4. On the day another vaccination is given and whilst experiencing the side effects of another vaccination

GRAZAX should be restarted once the patient has recovered completely from the above listed conditions.

5. Infections/inflammation/bleeding/wounds/ulcers in the mouth (for example, cold sores, dental extraction, trauma to mouth during sports injury)

GRAZAX should be restarted after the wounds in the mouth have healed and 7 days after tooth extraction.

How should GRAZAX be re-started after a break or a missed dose?

DO NOT take a double dose.

If the treatment is interrupted for less than 10-14 days the treatment can be re-started at home. Simply take your 1 tablet per day as usual.

If the treatment has been interrupted for more than 10-14 days then treatment should be re-started under supervision in the hospital. Please inform your allergist or allergy specialist nurse.

How to store GRAZAX

Keep out of reach of children.

Store in safe dry place at room temperature. You do not need to keep GRAZAX in the refrigerator.

Open each blister just before you take the tablet. DO NOT take tablets out of the blisters to store in a pillbox.

Repeat prescription

It is the family's responsibility to phone the provider of repeat GRAZAX prescriptions well in advance before running out of tablets. In order to avoid interruption of treatment we advise that the family phones to re-order next prescription on the day they open the last 30 tablet pack.

Could any new medications be started whilst on GRAZAX?

You MUST discuss with your allergist before starting any new medications or having other vaccines. **At any time during the treatment period of 3 years, PLEASE REMEMBER to inform your allergist of any new medications you are advised to take.**

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