

## Prescribing Guidance – Grazax® 75,000SQ-T to reduce allergy symptoms caused by a specific allergen (Grass Pollen)

September 2025 v1.0

**Grazax® is used to treat rhinitis and conjunctivitis caused by grass pollen in adults and children over 5 who have failed to respond to anti-allergy drugs.** It can be used for patients who have:

- Been diagnosed by clinical history and a positive test of grass pollen (skin prick test or specific immunoglobulin E [IgE]) and
- persistent symptoms despite use of symptom-relieving medicine

Treatment will be initiated by a clinician in the allergy clinic. They will monitor patient and provide medication for the first month. GP will be asked to prescribe thereafter.

**AMBER - SPECIALIST INITIATION: Specialist Allergy Clinic to monitor patient and provide medication for the first month. GP to prescribe thereafter.**

### Background

Grazax® is used to treat seasonal allergic hay fever caused by grass pollen. It is considered when patient:

- has responded poorly to both steroid nasal sprays and antihistamines
- is allergic, or having allergy testing to an allergen such as grass
- has severe symptoms caused by that allergen, such as hay fever

Grazax® should not be used for severe reactions to insects, eczema or food allergies. It is not licensed for treating asthma.

NICE has not yet published any guidance on the use of Grazax®.

### Procedure

Treatment is initiated by an allergy specialist 4 months before the grass pollen season begins. It should be continued all year round for a total of 3 years. Specialist will review patient at the end of the pollen season. If symptoms have not improved, treatment may be stopped.

Grazax® comes as a daily sublingual tablet. One or two hours before taking Grazax®, patient should be advised to take an antihistamine.

The first Grazax® dose will be administered in the allergy clinic to ensure that the tablet is taken correctly. Patient will be monitored for any side effects. Before initiation, patient will be asked to complete a consent form, and they will have pulse, blood pressure and peak expiratory flow rate (PEFR) checked.

Tablets must be taken out of the packet with dry fingers and placed under the tongue. Patient should avoid eating or drinking for at least 5 minutes to ensure the tablet is completely dissolved.

On the second or third day after starting the medication, patient will be asked to phone or email the allergy clinic to discuss treatment and to report any side effects or concerns. Adverse effects can also be reported via the Yellow Card scheme - <https://yellowcard.mhra.gov.uk/>

Patient's regular GP will be asked to continue to prescribe Grazax®, as well as any rescue medication for breakthrough symptom relief, as advised by the specialist.

If Grazax® treatment is interrupted for up to 7 days, it can be continued by the patient. If the treatment is interrupted for more than 7 days, it is recommended to contact specialist for advice before resuming.

## Side effects

The most common side effects of treatment with Grazax® are runny nose and watery eyes. These symptoms should be expected and are more common in the first few weeks of treatment. Patient usually gets these straight after taking the first tablet and they do gradually fade.

Very rarely, patients may experience potentially severe side effects including:

- Feeling lightheaded or faint
- Rapid swelling of the face, mouth or throat
- Fast, shallow breathing or other breathing difficulties
- Wheezing
- A fast heartbeat
- Clammy skin
- Anxiety and confusion
- Collapsing or losing consciousness

If any of these symptoms occur, patient should stop treatment and seek medical help immediately by calling 999 or going to local Accident and Emergency department.

For any other non-urgent symptoms please inform the allergy clinic or GP/Pharmacist.

## Contraindications

It is important for the patient to continue other prescribed medications.

Grazax® should not be taken if patient has cancer/ malignancy, severe asthma, severe inflammation of the mouth (for example cuts or sores) or an illness which affects the immune system.

Patients with uncontrolled or severe asthma (in adults: FEV<sub>1</sub> < 70% of predicted value after adequate pharmacologic treatment, in children: FEV<sub>1</sub> < 80% of predicted value after adequate pharmacologic treatment) should not be treated with Grazax®.

Grazax® contains fish-derived gelatine. Although there does not appear to be an increased risk of allergic reactions in patients with fish allergy, patient should inform specialist allergy team if they think they may be affected.

No studies investigating drug interactions have been conducted in humans.

## Special Care and Vaccinations

Rare cases of serious anaphylactic reactions have been reported. Therefore, medical supervision at start of treatment is an important precaution. In some cases, the reaction has occurred after the initial dose.

Serious anaphylactic reactions may be treated with adrenaline. Consider whether your patient would be able to tolerate adrenaline:

- Effects of adrenaline may be increased in patients treated with tricyclic antidepressants, mono amino oxidase inhibitors (MAOIs) and/or COMT inhibitors
- Effects of adrenaline may be reduced in patients treated with beta-blockers.

Special care is required if patients are due to have dental surgery. Grazax® should be stopped for 7 days afterwards. This also applies to young children who lose their milk teeth.

Patients with cardiac disease may be at increased risk in case of severe systemic allergic reactions. Clinical experience with treatment with Grazax® in patients with cardiac disease is limited.

Asthma is a known risk factor for severe systemic allergic reactions. Grazax® has not been studied in patients with severe and uncontrolled asthma.

Vaccinations may be given without interrupting treatment, although patient should be reviewed first. Allergy clinic should be informed if vaccinations are planned.

## Pregnancy, breastfeeding and fertility

### Pregnancy

Treatment with Grazax® should not be initiated during pregnancy because of the risk to the baby should a severe reaction occur. There is limited evidence about use in pregnancy. If patient becomes pregnant, or they are thinking about getting pregnant, they should inform the allergy clinic as treatment may be stopped.

If pregnancy occurs during treatment, the treatment may be stopped after evaluation of the general condition (including lung function) of the patient and reactions to previous administration of Grazax®.

### Breastfeeding

No clinical data is available for the use of Grazax® during lactation. No effects on the breastfed infants are anticipated.

### Fertility

There is no clinical data with respect to fertility for the use of Grazax®.

## Summary Table

Stage of Treatment	Allergy Clinic	General Practitioner
Initiation	<ul style="list-style-type: none"><li>• Pre-treatment questionnaire. Following assessment and written consent, first tablet given under supervision. Patient observed for a minimum of 1 hour.</li><li>• Once stable, transferred to maintenance dose of 1 tablet daily, self-administered at home.</li><li>• First month to be prescribed by specialist.</li><li>• Letter to GP advising date of commencement and relevant information</li><li>• Clinic contact details provided to patient.</li></ul>	<ul style="list-style-type: none"><li>• GP to prescribe after first month treatment.</li><li>• GP to prescribe any rescue medication for break through symptom relief, as advised by specialist.</li></ul>
Review	<ul style="list-style-type: none"><li>• Follow-up review appointment arranged for 5 to 6 months after start of treatment.</li><li>• Post treatment questionnaire to evaluate effectiveness of treatment.</li><li>• Decision made regarding continuing therapy Inform GP.</li></ul>	
Maintenance	<ul style="list-style-type: none"><li>• Further annual assessment and review by clinic during 3-year course of treatment.</li><li>• Advise GP for end date for treatment.</li></ul>	<ul style="list-style-type: none"><li>• GP to prescribe SLIT for remainder of 3-year course and any symptomatic treatment.</li></ul>

Adapted for local use from guidance below:

- Grazax hay fever treatment – Guy's and St Thomas' NHS Foundation Trust - <https://www.guysandstthomas.nhs.uk/health-information/granax-hay-fever-treatment> - accessed 29/9/2025
- Grazax treatment for patients with severe seasonal allergic rhino conjunctivitis (hay fever) – Cambridge University Hospital <https://www.cuh.nhs.uk/patient-information/granax-treatment-for-patients-with-severe-seasonal-allergic-rhino-conjunctivitis-hay-fever/> – accessed 29/9/2025
- Grazax® SPC - <https://www.medicines.org.uk/emc/product/315/smpc> - accessed 29/9/2025

<b>Title</b>	Prescribing Guidance - Sublingual Immunotherapy (SLIT) – Grazax® to reduce allergy symptoms caused by a specific allergen
<b>Description of policy</b>	To inform healthcare professionals
<b>Scope</b>	Norfolk and Waveney Integrated Care System
<b>Prepared by</b>	Norfolk and Waveney ICB Medicines Optimisation Team
<b>Impact Assessment</b> (Equalities and Environmental)	Please indicate impact assessment outcome: <b>Positive impact</b> Adverse impact - low - action plan completed as per guidance Adverse impact - medium - action plan completed as per guidance Adverse impact - high - action plan completed as per guidance No impact <b>No policy will be approved without a completed equality impact assessment</b>
<b>Other relevant approved documents</b>	Formulary application presented to TAG for Grazax
<b>Evidence base / Legislation</b>	Level of Evidence: A. based on national research-based evidence and is considered best evidence <b>B. mix of national and local consensus</b> C. based on local good practice and consensus in the absence of national research-based information.
<b>Dissemination</b>	Is there any reason why any part of this document should not be available on the public web site? <input type="checkbox"/> Yes / No <input checked="" type="checkbox"/>
<b>Approved by</b>	Norfolk & Waveney Therapeutics Advisory Group (TAG) (October 2025)
<b>Authorised by</b>	Norfolk & Waveney Medicines Optimisation Programme Board (MOPB) on behalf of the ICS (October 2025)
<b>Review date and by whom</b>	Therapeutics Advisory Group (Oct 2027)
<b>Date of issue</b>	October 2025

<b>Version Number</b>	<b>Author</b>	<b>Purpose / Change</b>	<b>Date</b>
1.0	Specialist I+F Technician, NWICB	New document to support prescribers with SLIT	Oct 2025