

# Prescribing Framework for Sublingual Immunotherapy (Grazax)

| Patient's Name:NHS Number:                                       |              |  |
|--|--------------|--|
| Patient's Address:(Use addressograph sticker)                    |              |  |
|  |              |  |
|  |              |  |
|  |              |  |
| GP's Name:   |              |  |
|  |              |  |
| Communication  |              |  |
|  |              |  |
| We agree to treat this patient within this Prescribing Framework |              |  |
| Specialist Prescriber's Name                                     | Prof Reg. No |  |
| Specialist Prescriber's Signature                                | Date:        |  |
| Where prescriber is <u>not</u> a consultant:                     |              |  |
| Consultant's Name:   | GMC No       |  |
| Consultant's Signature   | Date:        |  |
|  |              |  |
| GP's Signature:  | Date:        |  |
| GP's Name (if different from listed above)                       |              |  |

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.

The patient's GP should sign and send back to specialist, to confirm agreement to enter into shared care arrangement. If the General Practitioner is <u>unwilling</u> to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

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Full copy of framework can also be found at: http://www.hey.nhs.uk/amber.htm

#### 1. Background

Immunotherapy is the only treatment to affect the underlying allergic reactivity. It involves treating the patient with the allergen to desensitise the immune system. Injection immunotherapy has been the standard treatment and involves monthly injections over 3 years. The efficacy of this treatment has been investigated thoroughly and confirmed by a Cochrane review.

Grazax is a sublingual immunotherapy tablet which contains an allergen extract of grass pollen. The treatment is intended to increase the tolerance towards grass pollen, and thereby reduce allergic symptoms.

Though confirmed as effective compared with placebo, no comparison has been done with injection immunotherapy.

The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL (91) 127 "Responsibility for prescribing between hospitals and GPs".

#### 2. Indication

Adults and children 5 years and over with severe grass pollen allergy or seasonal asthma who have failed all symptomatic therapies. Patient's requiring oral steroids for treatment of seasonal symptoms.

#### 3. Dose

Daily sublingual dose of 75,000 SQ-T(1 sublingual tablet)

To get the best effect treatment should ideally be started at least 4 months prior to the expected start of the grass pollen season.

#### 4. Duration of treatment

1 tablet daily for 3 years.

N.B. This is continuous treatment NOT just in grass pollen season.

#### 5. Contraindications / cautions

Contraindicated in:

- pregnancy
- Severe fish allergy
- individuals who have had previous allergic reaction to grass pollen injection immunotherapy
- malignancy or severe disease affecting immune system
- inflammatory condition in oral cavity with severe symptoms.

In case of oral surgery, including dental extraction, and shedding of a deciduous tooth in children, treatment with Grazax should be stopped for 7 days to allow healing of the oral cavity.

### 6. Adverse effects

Very common - Itching in mouth, ears, irritation of throat, sneezing and swelling in mouth Common - Gastrointestinal symptoms such as stomach pain, nausea and heart burn. Uncommon – More severe local symptoms in mouth and throat. Potential for more widespread allergy including anaphylaxis if highly sensitive. No known long term side effects.

### 7. Interactions

No known interactions.

## 7. Monitoring

See below

**8. Information to patient** Verbal explanation of treatment plus written product information provided by Immunology Department. Clinic contact details also provided.

## 9. Responsibilities of clinicians involved

| Stage of Treatment | Hospital Specialist   | General Practitioner  |
|--------------------|---|---|
| Initiation         | Pre treatment questionnaire regarding symptoms and medication usage completed by patient. Following assessment and written consent 1st tablet self administered in Immunology outpatient department under supervision. Patient observed for any adverse effects for a minimum of 1 hour. Once stable transferred to maintenance dose of 1 tablet daily self administered at home.  First month to be prescribed by specialist.  Letter to GP advising date of commencement of treatment and copy of shared care agreement.  Clinic contact details provided to patient. | GP to prescribe after first month treatment.  GP to prescribe any rescue medication for break through symptom relief, as advised by specialist. |
| Review             | Post seasonal follow up review appointment arranged. Post treatment questionnaire to evaluate effectiveness of treatment. Decision made regarding continuing therapy and inform GP.   |   |
| Maintenance        | Further annual assessment and review by Immunology service during 3 year course of treatment.  Advise GP for end date for treatment.  | GP to prescribe Grazax for remainder of 3 year course and any symptomatic treatment.  |

#### **Contact Details:**

Dr Pavel Gordins Consultant Immunologist During office hours via secretary – 01482 461312.

Dr Sujoy Khan, Consultant Immunologist During office hours via secretary – 01482 461312

Dr Vikas Gupta, Consultant Paediatrician During office hours via secretary – 01482 602769

Immunology specialist nurses During office hours – 01482 461079

## **APPROVAL PROCESS**

| Written by:           | Jackie Moor, Immunology Specialist Nurse  |
|-----------------------|---|
|                       | Marie Miller, Interface Pharmacist        |
|                       | Reviewed Dec 13, Jane Morgan, Interface   |
|                       | Pharmacist May 17, April 2020             |
| Consultation process: | Immunology Specialist Team and Consultant |
|                       | Paediatrician May 17                      |
| Approved by:          | MMIG Jan 14, LMC Jan 14, MMIG June 17 May |
|                       | 2020                                      |
| Ratified by:          | HERPC May 2020                            |
| Review date:          | May 2023                                  |

Prescribing framework for Grazax
Date approved by the HERPC: May 2020 Review date: May 2023
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