Therapeutics Advisory Group



Prescribing Guidance - Sublingual Immunotherapy (SLIT) - Acarizax to reduce allergy symptoms caused by a specific allergen

As per NICE <u>TA1045</u>, 12 Standard Quality House Dust Mite (SQ-HDM) SLIT (**Acarizax**®) is recommended for use in people aged 12 to 65 years with **allergic rhinitis** that is:

- diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test or specific immunoglobulin E [IgE]) and
- persistent despite use of symptom-relieving medicine

Please note NICE does not recommend use of Acarizax® for treating house dust mite **allergic asthma** in adults, so it will remain **BLACK Not Commissioned** for this indication.

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

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

Background

Sublingual immunotherapy, or SLIT, is a course of treatment given to reduce allergy symptoms or allergic rhinitis and/or conjunctivitis caused by a specific allergen. It is considered when patient:

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

A SLIT course lasts about 3 years. Treatment is given as liquid drops or a tablet.

- For hay fever due to grass or tree pollens, it is started a few months before the pollen season.
- For allergens that last all year, such as house dust mites or animal furs, it can be started at any time of the year.

SLIT is not available for treating severe reactions to insects, eczema or food allergies, and it is not licensed for treating asthma.

Clinical trials have shown SLIT reduces symptoms and is safe for people with grass allergic hay fever and house dust mite allergy. The benefits last for many years (up to 10 years in one study) after the 3-year treatment programme has been completed. However, benefit cannot be guaranteed in everyone. SLIT is a convenient treatment option, with less hospital visits compared to injections.

Acarizax® is used for house dust mite allergy, for severe symptoms that have not responded to usual treatments. It reduces allergic symptoms by giving patient a regular fixed amount of house dust mite allergy extract, allowing the immune system to build up a natural tolerance to house dust mite allergy.

Procedure

Acarizax® is taken daily and dissolved under the tongue.

Acarizax® treatment can be initiated any time of the year and should be continued all year round for a total of three years.

One or two hours before starting SLIT, patient should have an antihistamine. The first SLIT dose will be administered in the hospital's allergy clinic by a doctor or nurse. This is to ensure that the tablet is taken correctly, to monitor any side effects and to give patient the opportunity to discuss possible side effects. Before taking the first tablet, patient will be asked to complete a consent form, and they will have pulse, blood pressure and peak expiratory flow rate (PEFR) checked.

Patient should be advised to avoid swallowing for one minute and avoid food and drink for five minutes after taking the tablet. They will be asked to remain in the department for at least one hour under observation. They should be able to take subsequent doses at home. On the second or third day after starting the medication, they will be asked to phone or email the allergy department to report any side effects or symptoms. The specialist will review the patient after 4 months treatment and confirm ongoing treatment, and they will confirm and advise GP of expected course completion date. After that, patient will be reviewed annually by the specialist allergy team.

The regular GP will be asked to continue to prescribe the medication. GP should also prescribe any rescue medication for break through symptom relief, as advised by the specialist.

There is no additional monitoring required in primary care.

If treatment is interrupted for a period up to 7 days, treatment can be resumed by the patient. If the treatment is interrupted for more than 7 days, it is recommended to contact specialist allergy service before resuming.

Side effects

The most common side effect of treatment with SLIT is itching and swelling of the mouth. These symptoms should be expected and are more common in the first few weeks of treatment. Patient should be advised to take regular antihistamines during the first month of treatment to prevent these symptoms. Some also experience tiredness in the first few weeks.

Very rarely patients may experience potentially severe side effects including:

- · difficulty swallowing
- · difficulty breathing
- widespread itchy rash
- severe dizziness

If any of these symptoms occur, you should not take any further treatment and seek medical help immediately by calling 999 or going to your local Emergency Department.

For any other non-urgent symptoms please inform the Allergy clinic.

Contraindications

It is important for the patient to continue other prescribed medications, including medication to treat hay fever, asthma and other allergic conditions. They should be advised to inform the allergy clinic if their medications change before or after initiation of treatment.

SLIT should not be taken if patient has cancer / malignancy, severe asthma or severe inflammation of the mouth (for example cuts or sores). If patients with concomitant asthma experience symptoms and signs indicating asthma deterioration, they should consult Specialist Allergy Service as treatment may need to be interrupted or discontinued.

The tablets contain fish-derived gelatine and although there does not appear to be an increased risk of allergic reactions in those with fish allergy, patients should inform the Allergy Service if they are aware that they suffer from this.

Special Care and Vaccinations

Special care is required if patient has had had recent dental surgery, they have a severe allergy to fish or they have experienced severe allergic reactions to house dust mite immunotherapy injections previously. They should contact the allergy clinic for advice if any of those apply.

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

Pregnancy and breastfeeding

Pregnancy

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

If pregnancy occurs during treatment, the treatment may continue after evaluation of the general condition (including lung function) of the patient and reactions to previous administration of SLIT. In patients with pre-existing asthma, close supervision during pregnancy is recommended.

Breastfeeding

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

Fertility

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

Summary Table						
Stage of Treatment	Allergy Clinic	General Practitioner				
Initiation	 Pre-treatment questionnaire. Following assessment and written consent, first tablet given under supervision. Patient observed 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 and relevant information 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 Inform GP. 					
Maintenance	 Further annual assessment and review by clinic during 3-year course of treatment. Advise GP for end date for treatment. 	GP to prescribe SLIT for remainder of 3-year course and any symptomatic treatment.				

Adapted for local use from guidance published by:

- Cambridge University Hospitals <u>Acarizax treatment for patients with severe house dust mite allergy | CUH</u> (accessed 31/3/2025)
- University Hospitals Coventry and Warwickshire Patient advice on the use of Grazax/ Acarizax (accessed 31/3/2025)
- Acarizax SPC <u>ACARIZAX 12 SQ-HDM Summary of Product Characteristics (SmPC) (emc) | 12905</u> (accessed 31/3/2025)
- Hull and East Riding Prescribing Committee <u>Prescribing Framework for Sublingual Immunotherapy</u> (<u>Grazax</u>) (accessed 31/3/2025)

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

Version Number	Author	Purpose / Change	Date
1.0	Senior I+T Technician, NWICB	New document to support prescribers with SLIT	June 2025