

Tablet SLIT SOP

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Guidelines for the patient selection and administration of tablet SLIT

These should be read in conjunction with the SIT SOP, BSACI Immunotherapy Guidelines and BSACI SOP for administration of Sublingual Immunotherapy. Tablet SLIT contain allergens used as sublingual immunotherapy. The primary outcome is to desensitise the immune system so that it does not respond when challenged with grass pollen or other relevant allergen. Patients with rhinoconjunctivitis can benefit from this therapy as it can improve the quality of life by long term remission, symptom reduction, reduced need for symptom relieving drugs and the prevention of new sensitisations and allergic asthma.

Patient Selection

Tablet SLIT, in accordance with its marketing authorisation, is suitable for treating customers over the age of five years with grass pollen, over the age of eighteen years with birch pollen, or over the age of twelve years with HDM induced rhinitis and conjunctivitis whose symptoms are not controlled with regular, conventional pharmacotherapy or who wish for a more long-term treatment. In addition, patients may fall into one or more of the following categories:

- Mono-sensitised to grass pollen, birch pollen, or HDM or polysensitised with symptoms predominantly related to any of the three mentioned allergens
- Patients who have suffered any severe adverse reaction to SCIT
- Patients who cannot undertake SCIT for insurmountable logistical reasons (distance, time, working hours, etc).

Treatment regime

Frequency	Once daily
Route	Sublingual
Duration	Usually for up to 3 years

Scheduling start of treatment

Tablet SLIT can be commenced any time of year, pre-seasonally and co-seasonally. If commencing co-seasonally, it is worth making the patient aware of the possibility of increased symptoms during the first 1-2 weeks of treatment. There is good evidence that co-seasonal administration is just as effective and patients remain as compliant as pre-seasonal administration.

Onboarding

An assessment to ensure the patient is suitable and appropriately well enough to commence treatment. The assessment should consider:

- Symptoms consistent with seasonal/perennial allergic rhinitis caused by the relevant allergen
- A positive skin prick or blood test, confirming the allergen responsible for symptoms
- Appropriate use and effectiveness of other pharmacological treatments such as antihistamines and intranasal corticosteroids
- Contraindications
 - Relative:
 - Beta-blockers - at the clinician's discretion. Typically, this is discontinued for a few days prior to first dose allergen exposure to mitigate risks concerning the potential need for adrenaline. Cardioselective beta-blockers pose a lesser risk. Discussion with their cardiologist can be considered in this circumstance but in particular if the customer is on beta-blockers for a condition like SVT, and the benefits/risks need weighing up.
 - Stable autoimmune disease - at the clinician's discretion. Escalate to an AllergyRhino specialist if unsure
 - Malignancy in remission - at the clinician's discretion. Escalate to an AllergyRhino specialist if unsure
 - Known hypersensitivity to any of the excipients, particularly fish allergies - escalate to an AllergyRhino specialist in these cases
 - Absolute:
 - Known active malignancy or systemic disease affecting the immune system e.g. autoimmune diseases, immune complex diseases or immune deficiency diseases
 - A clinical history suggestive of active asthma (interval symptoms, increased use of a bronchodilator, or FEV1 <80%) should result in

administration of Tablet SLIT becoming postponed until their asthma is well controlled.

- A severe asthma exacerbation within the last 3 months
- Discontinue in customers with asthma whose asthma is severely exacerbated
- A quality of life questionnaire and visual analogue scale will be completed by the customer, relating to the preceding season.
- The patient will be counselled as to the risks and benefits of taking Tablet SLIT. Tablet SLIT will be administered as per manufacturers guidelines.
- For the first dose of Tablet SLIT, the patient will be shown how to take the medication and will then be observed by a healthcare professional for 30 minutes for any sign of an allergic reaction. In cases where there are no symptoms at all, the patient does not require observation for the full 30 minutes. Observations can take place in a central location of the patient's choosing, from a list AllergyRhino offers. Alternatively, a home visit can be arranged for an observed first dose. In select cases, where there is concern about increased sensitivity, patients will be commenced on a quarter or half tablet for their first dose. This is then titrated upwards over the course of 1-2 weeks into a full dose
- Patients will be given an initial 1 month supply of treatment. Following 3 weeks of treatment, the patient will then be provided with rolling 3 month supplies until the full course has elapsed.

First dose administration

Although sublingual immunotherapy is accepted to be safe and there are no case reports of mortality under conditions of normal usage, there remains a theoretical risk of anaphylaxis that clinicians and patients must be aware of.

It is recommended that sublingual immunotherapy should be initiated in an area that has minimal distractions and where there is an appropriate third party that is equipped to manage anaphylaxis.

Drug	Dose
Adrenaline (autoinjector)	>12 years 500mcg (0.5ml) 6-12 years 300mcg (0.3ml) <6 years 150mcg (0.15ml)

Chlorphenamine	>12 years 4mg 3-6 times a day 6-12 years 2-4 mg 3-4 times a day <6 years 1-2mg 3 times a day
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The patient should be informed of the theoretical risk of anaphylaxis and consent should be obtained from the patient or in the case of a child, a carer with parental responsibility and assent given by the child.

Patients should be advised that they must be well on the day of administration and if they have asthma this should be well controlled.

1. Check patients' name and DOB against the prescription to confirm that SLIT is being administered to the correct patient.
2. Complete a visual inspection of the mouth, observing for oral lesions or loose teeth.
3. Confirm that the patient is not pregnant.
4. The patient should refrain from eating and drinking for five minutes prior to and following administration of SLIT.
5. Advise the customer they will experience side effects such as oral tingling, pruritus, mild tongue swelling, itchy throat or ears and that this is normal and expected.
6. Break the SLIT tablet in half. Administer the half tablet by placing the treatment in the sublingual pocket under the base of the tongue. Please see individual SPC for product-specific advice.
7. SLIT should remain under the tongue for between 1–2 minutes before swallowing.
8. Monitor the patient for any sign of an allergic reaction for 30 minutes following administration of SLIT.
9. If commencing two separate SLIT products on the same visit, there should be 30–60 minutes between giving the first product and the second. A further 30–60 minutes observation should occur after the second product is given.
10. Reassure the customer if they experience symptoms described above
 - a. These are common side effects and should resolve 1–2 weeks after beginning SLIT.
11. Promptly treat any allergic reaction or side effects of SLIT.
12. Advise the patient that if side effects are unpleasant, they can take an oral non-sedating antihistamine 30–60 minutes prior to taking their SLIT medication.
13. Advise the patient to stop taking SLIT in the following situations:
 - a. For 7 days following oral surgery, including dental extraction.
 - b. For 7 days after shedding a deciduous tooth.

- c. If the patient has an oral ulcer or open wound in the mouth or oral mucosa – to temporarily discontinue SLIT until the area has healed.
 - d. If the patient is unwell with a fever or unwell enough to be absent from school or work, they should temporarily discontinue their SLIT until their illness has resolved.
 - e. If the patient receives a vaccine that causes side effects such as fever or joint pain, they should stop their treatment until the side effects resolve.
 - f. patients with concomitant asthma experiencing an acute upper respiratory tract infection – to temporarily discontinue until the infection has resolved.
14. Document administration of SLIT, any side effects, and treatment given.
15. Ensure the patient and/or family have the following information on discharge:
- a. How to recognise and manage an allergic reaction.
 - b. Advise the patient to ensure they have immediate access to a non-sedating antihistamine.
 - c. Revision and reinforcement of the importance of compliance with medication.
 - d. Have a supply of initial treatment and awareness of how to collect ongoing supply.
 - e. Written information relating to the product they are using.
 - f. Contact details should they require ongoing support which can be found on the AllergyRhino website.
 - g. An expected schedule for how and when they will be followed up, and how they will receive the supply of SLIT medication.
16. Advise the patient to continue taking SLIT daily as prescribed (typically for the next 3 years).
17. Follow up the patient as appropriate.

Reviews

Patients will be reviewed at 3 months, 6 months, 1 year, 2 years and then at the end of the course at 3 years.

Compliance, symptoms and QOL will be assessed regularly using a compliance and symptoms questionnaire at month 0, 1, 2, 3, 4, 5, 6, 9, 12, 18, 24, and 36.

Any side effects the patient is experiencing will be discussed at reviews. Postpone treatment with Tablet SLIT in the following scenarios:

- Known acute severe oral inflammation or oral wounds
- Patients experiencing an acute respiratory tract

- In patients with severe oral inflammation (e.g. oral lichen planus, mouth ulcers or thrush), oral wounds or following oral surgery, including dental extraction, or following tooth loss, postpone Tablet SLIT temporarily to allow healing of the oral cavity.
- In customers with severe or persisting gastroesophageal symptoms such as dysphagia or dyspepsia, discontinuation of treatment with Tablet SLIT should be considered due to isolated cases of eosinophilic oesophagitis. In customers with mild to moderate symptoms, advise the customer to try taking their SLIT just after a meal and to drink plenty of water 5 minutes after their dose.

Patient support

Patients will be given a patient information email to supplement the advice already given. In addition, they will receive the contact details of a suitable AllergyRhino representative, should they have any queries or concerns during the course of treatment.

Common complaints and their resolutions include:

- In cases of intense oral and pharyngeal pruritis - administer a quarter or half a tablet, wait 5 minutes, and then drink water to reduce symptoms. Continue reduced dosing at home and increase dose as symptoms improve. Remain in communication with the AllergyRhino clinical team during this process.