



Please read and be certain that you understand the following information prior to signing this Consent for Treatment

Purpose

The purpose of sublingual immunotherapy (SLIT / allergy drops) is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergen (pollen, mold, mites, animal dander, etc.) will result in fewer and less severe symptoms. This does not mean that sublingual immunotherapy is a substitute for avoidance of known allergens or for the use of allergy medications, but rather is a supplement to those treatment measures.

Sublingual immunotherapy has been shown to lead to an alteration of your immune system's response to naturally occurring allergens. These alterations may permit you to tolerate exposure to the allergen with fewer symptoms. You, in effect, become "immune" to the allergen. The amount of this immunization is different for each person and is, therefore, somewhat unpredictable.

Indications

To qualify for immunotherapy, there must be documented allergy to substances in the environment that cannot be avoided. Documentation of allergy can be either in the form of a positive skin test or a positive blood test. In addition to demonstrable allergy by one of the above tests, problems such as hay fever or asthma should occur upon exposure to the suspected allergen. Due to the inherent risks of immunotherapy, avoidance measures and medical management should usually be attempted first.

Efficacy

Improvement in your symptoms will not be immediate. It usually requires *3 to 6 months* before any relief of allergy symptoms is noted, and it may take *12-24 months* for full benefits to be evident. About 85-90% of allergic patients on immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always completely eliminated.

Procedure

Sublingual immunotherapy is usually begun at a very low dose. This dosage is gradually increased on a regular basis until a therapeutic dose (often called the "maintenance dose") is reached. The maintenance dose may differ from person to person. SLIT is typically given daily. This frequency reduces the chances of a reaction and permit's the maintenance dose to be reached within a reasonable amount of time. After the maintenance dose is determined, SLIT is usually continued on a daily basis.

Duration of Treatment

It usually takes about 10 days to reach a maintenance dose. The time may be longer if there are extract related reactions or if the drops are not received on a regular basis. For this reason, it is important that the recommended schedule be followed. If you anticipate that regular dosing cannot be maintained, immunotherapy should not be started. Immunotherapy may be discontinued at the discretion of ENT & Allergy Specialists if immunotherapy is frequently missed, as there is an increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for at least 1 year, after which the need for continuation is reassessed. A typical course of treatment is around 4 years.

Adverse Reactions

Immunotherapy is associated with some widely recognized risks. Risk is present because a substance to which you are known to be allergic is being administered to you. Some adverse reactions may be life-threatening and may require *immediate medical attention*. In order of increasing severity, the following brief descriptions explain the nature of these potential reactions:

A. Local Reactions

Local reactions are common and are usually restricted to the lips and mouth. You may experience oral itching or GI upset. These reactions are more likely to occur as you reach higher doses. The reactions may occur immediately after administering your drops or several hours after. Symptoms can usually be treated successfully with oral antihistamines.

B. General Reactions

Generalized reactions occur rarely but are the most important because of the potential danger of progression to collapse and death if not treated. These reactions may include:

1. **Urticarial reactions** (hives) include varying degrees of rash, swelling, and/or itching of more than one part of the body. There may be mild to moderated discomfort, primarily from the itching. This uncommon reaction may occur within minutes to hours after a dose.
2. **Angioedema** is rare and is characterized by swelling of any part of the body, inside or out, such as the ears, tongue, lips, throat, intestine, hands or feet, alone or in any combination. This may occasionally be accompanied by asthma and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principle danger lies in suffocation due to swelling of the airway. Angioedema may occur within minutes after the drops are administered and requires immediate medical attention.
3. **Anaphylactic shock** is the rarest complication, but is a serious event characterized by acute asthma, vascular collapse (low blood pressure), unconsciousness, and potentially death. This reaction usually occurs within minutes of the dose and is extremely rare.

The above reactions are unpredictable and may occur with the first dose or after a long series of doses, with no previous warning. All generalized reactions require *immediate evaluation and medical intervention*. If a localized or generalized reaction occurs, the vaccine dosage will be adjusted for subsequent doses. Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction. As an additional precaution, the physicians of ENTAS require all immunotherapy patients to carry an emergency epinephrine auto injector on the days they receive immunotherapy.

Observation Period Following Drops

Patients receiving immunotherapy, receiving first dose from a new bottle should wait in the clinic area for **20 minutes**. If you have a reaction, you may be advised to remain in the clinic longer for medical observation and treatment. If a generalized reaction occurs after you have left the clinic area, you should **immediately go to the nearest emergency medical facility**. There are several allergy extract-related deaths each year in the United States. While most systemic reactions are not life-threatening if treated promptly, this fact stresses the importance of remaining in the clinic for the suggested observation time. If you do not remain in the clinic area for the designated time, the doctor may recommend discontinuation of immunotherapy.

Important Information Concerning Your SLIT Extract Prescription

The acquisition and use of your specific SLIT extract prescription bottles will be discussed with you by our staff. Currently, no U.S. Food and Drug Administration (FDA) –licensed extracts or American Medical Association Current Procedural Terminology (CPT) codes are available for sublingual immunotherapy (SLIT) use in patients in the United States. In addition, this treatment is considered to be investigational and off-label in the United States for the products being used, and, although SLIT is considered much safer than SCIT, the dose required for efficacy are much higher than when employing injection therapy. As a result, it is unlikely that any U.S. health insurance policy will cover the expenses related to SLIT. Each allergen vaccine bottle carries an expiration date: doses should not be administered from expired bottles.

Pregnancy

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the allergy technicians immediately, so that ENT & Allergy Specialists can determine an appropriate dosage schedule during pregnancy. Immunotherapy doses will not be advanced during pregnancy, but may be maintained at a constant level as long as your OBGYN sends a note to ENTAS stating that it is ok to continue immunotherapy.

Medications

Please notify the office staff if you start any new prescription medication, particularly medication for high blood pressure, migraine headaches, and glaucoma. “Beta blocker” medications are contraindicated while on immunotherapy, and your immunotherapy will need to be discontinued while you are taking a beta blocker.

Administration of SLIT

If dosing is to be done at home, it is recommended that you do so during our usual office hours, so that our staff will be immediately available by phone for questions or emergencies.

Office Hours

Allergy Technicians are available Monday – Friday from 9:00am until 5:00pm at 859-781-4900 should you have any questions.

If you have any questions concerning anything in the *Consent for Immunotherapy*, please direct the questions to the Allergy Technicians or your ENT & Allergy Specialists physician. If you wish to begin immunotherapy, please sign the *Authorization for Treatment* (below) and return it to our allergy department. Thank you.

Consent for Administration of SLIT/sublingual immunotherapy Authorization for Treatment

I have read the information in this consent form and understand it. The opportunity has been provided for me to ask questions regarding the potential risks of sublingual immunotherapy (SLIT), and these questions have been answered to my satisfaction. I understand that precautions consistent with the best medical practice will be carried out to protect me from adverse reactions to immunotherapy. I do hereby give consent for the patient designated below to be given immunotherapy (SLIT) over an extended period of time and at specified intervals, as prescribed.

_____	_____	_____
Printed Name of Immunotherapy Patient	Patient Signature (or Legal Guardian)	Date

Office Use Only Below This Line:

I certify that I have counseled this patient and/or authorized legal guardian concerning the information in the Consent for Immunotherapy (SLIT) and it appears to me that the signee understands the nature, risks, and benefits of the proposed treatment plan.

_____	_____
Allergy Technician Signature	Date