

Sublingual Immunotherapy (SLIT) Informed Consent

What is Sublingual Immunotherapy (SLIT)?

Sublingual Immunotherapy (SLIT), also known as Oral Immunotherapy or Allergy Drops, is an alternative to allergy shots and involves placing drops of allergen extracts under your tongue. The purpose of this treatment is to decrease your sensitivity to airborne allergens (pollens, pets, dust mites, etc.) so that when you are exposed to these allergens, you will experience fewer or no allergic symptoms. These are the same extracts used for allergy shots, but are given daily under the tongue.

Who qualifies for SLIT?

You must have documented allergies by skin or blood test to airborne allergies with nasal or asthma symptoms due to these allergens. Both children and adults are candidates for SLIT.

Who does not qualify for SLIT?

You are at increased risk of a systemic reaction if you have poorly controlled asthma. Therefore, you should not start SLIT until your asthma is under good control. Pregnant women may continue SLIT, but should not start this treatment during pregnancy. SLIT may be contraindicated in people who take medications called beta-blockers, which are often used for high blood pressure, migraine headaches, or glaucoma. Avoid if you have eosinophilic esophagitis or if you have open sores in your mouth. You should inform your allergy provider if you become pregnant or if there is significant change in your medical condition.

How does it work?

Like allergy shots, SLIT slowly alters your immune system's response to allergens by inducing tolerance or immunity to the allergens in the drops. If effective, you should have fewer or no symptoms upon exposure to the allergens that trigger your symptoms.

How is it administered?

Allergen extract drops will be placed under your tongue for 2 minutes, and then swallowed. The first dose will be administered in the office and you will be observed for 30 minutes. You will continue advancing doses at home.

How effective is it?

Most clinical studies have shown improvement in symptoms and a decrease in need for medication in patients on SLIT. Adjustments can be made to your treatment extracts to achieve the maximum effectiveness. To determine if SLIT is effective for you, you should plan on taking the drops for at least one year and have regular follow ups with your allergy provider. Most experts recommend a 3-5 year course of treatment to get long-term benefits that extend beyond the treatment period.

Will I still need to take allergy medication?

During the initial months you may need to take the same medications as before. As the treatment begins to take effect, you will discuss decreasing the allergy medications with your allergy provider at your regular follow-up visits.

What are the side effects?

Mild side effects are common and include itching lips or mouth within minutes to hours of the dose. This can occur in up to 1/3 of patients, usually in the first 2 weeks of therapy and then goes away as therapy continues. These reactions may be treated with an oral antihistamine. We recommend taking a daily antihistamine for the first several weeks of SLIT to prevent these symptoms until you tolerate your maintenance dose. Moderate side effects occur rarely and can include:

- Lip swelling
- Eye itching, redness and swelling
- Sneezing, nasal itching, nasal congestion
- Hives, swelling
- Nausea, vomiting, abdominal cramping, diarrhea
- Asthma symptoms: cough, wheeze, shortness of breath

Severe side effects, such as a drop in blood pressure, are extremely uncommon and no fatalities have been reported from this form of treatment. For this reason, unlike allergy shots, we allow patients to take drops at home. However, all patients should be aware of allergic reactions and may choose to have injectable epinephrine available in case of a severe reaction (in Europe, epinephrine is not routinely provided. In the United States, it is more commonly provided. We recommend an epinephrine autoinjector, at least when you first start). If you have moderate or severe reactions you must contact the office and stop the treatment until you have met and discussed these reactions with your allergy provider.

Another rare, delayed reaction to SLIT is eosinophilic esophagitis. Basically, your esophagus gets a rash from swallowing the drops. Symptoms consist of heartburn or difficulty swallowing. Symptoms are not permanent and resolve with discontinuation of SLIT.

Is SLIT safe during pregnancy and nursing?

There is not data available on the safety of administering sublingual immunotherapy during pregnancy or nursing. It is important that women, who are on SLIT and know or believe they are pregnant, notify their allergy provider as soon as possible.

Is SLIT approved by the FDA?

No. While SLIT is the more common method of treatment of allergic diseases than allergy shots in Europe, and is gaining popularity in the U.S., at present, it is yet not approved by the FDA. . Therefore, it is still considered an investigational treatment and an off-label use of allergy extracts. Tablets containing grass, ragweed or dust mites that work through the same mechanism as SLIT, are FDA approved but will only treat one allergen at a time.

What does it cost? Will insurance cover SLIT?

Until the FDA approves SLIT, most insurance companies will not pay for the treatment itself. Out-of-pocket cost involves the preparation of each allergy solution, which will contain allergens to which you are allergic.

How does SLIT compare with traditional Allergy Shots?

While comparative studies are limited, both therapies provide clinical improvement. But most experts agree that traditional allergy shots appear slightly more effective than SLIT. However, SLIT appears to be safer. Therefore, a major benefit of SLIT is that the drops may be administered at home, as opposed to injections administered in a doctor's office. As a result, there is significant time and travel savings. There is also the savings of a co-payment for allergy injections.

What are the alternatives to SLIT?

Standard treatments for allergies include: allergy avoidance, medications, dissolving tablets, and traditional allergy shots. You should discuss these alternatives with your allergy provider.

What if I have additional questions?

You should feel free to contact your allergy provider with any further questions or concerns about SLIT.

Consent for Administration of Sublingual Immunotherapy (SLIT)

I have read the information in this consent form and understand it. I was given the opportunity to ask questions regarding the potential risks of SLIT and these questions have been answered to my satisfaction. I give consent for the patient designated below to be given allergen SLIT. I am aware that I am financially responsible for the patient-specific allergy solution prepared. Payment is expected before vials are prepared for you.

Patient Name (Print)/DOB

Patient or Parent/Guardian Signature

Witness

Date

Copy of signed form given to patient _____
Staff initials