

PATIENT NAME: _____ DATE OF BIRTH: _____ TODAY'S DATE: _____

Allergy Immunotherapy Patient Consent Form – Sublingual Allergy Drops

Your Problem

You have an allergy. An allergy is caused by your immune system, which protects you from harmful germs. When you have an allergy, your body's immune system responds to a harmless substance (called an allergen) as a threat. When this happens, you may have itching, swelling, shortness of breath, or other symptoms.

Your doctor thinks you should have sublingual immunotherapy (also called SLIT) to treat your allergy. The goal of this treatment is to train your immune system not to react to allergens.

The Procedure and Follow Up

With SLIT, you will take allergy drugs made just for you, based on what you are allergic to. These drugs will contain a dose of one or more allergens.

Your doctor will decide how strong your first dose should be. The drugs will be given as a drop of liquid under your tongue. This will be absorbed by your body. Your doctor will tell you how long to hold the dose under your tongue and how long you should wait before eating or drinking. The dose will start small and slowly increase until your body becomes used to it. When this happens, your allergies should get better, and you may be able to take less (or no) allergy drugs.

The first dose will be given to you in your doctor's office. If you do not have any problems with the dose, then you can take it at home. You **must** take a dose once a day unless told otherwise.

Risks and Common Problems

There are risks linked to this treatment, which include but are not limited to:

Anaphylactic shock: You may have wheezing, shortness of breath, or low blood pressure. You could pass out or die. This can happen in minutes, but it is very rare. This can happen to anyone who has allergies.

Angioedema: You could have swelling in any part of the body. If too much swelling happens in the mouth or throat, then you could have breathing problems. If this happens, then you will need care from a doctor right away. This is very rare and happens much less with SLIT than it does with shots.

Hives (welts): Raised bumps may form on your skin. This may happen in minutes or hours. If this happens, then you should tell your doctor.

Local reactions: Your lips, mouth, or ears may itch or swell. Your throat may feel rough. This may happen in minutes or hours. If this happens, then you can often treat this problem with an allergy drug like Benadryl.

If any of the problems listed above happen to you, then you may need to have more treatments or procedures. This means you may need to go to the hospital or stay in the hospital for longer than planned.



Other Choices

If you choose not to have SLIT, then you may have other options.

You could get shots or take drugs to treat your allergies. Shots may work as well or better than SLIT. Shots can only be given in your doctor's office. Your doctor will talk to you about this option.

Your doctor will let you know what other choices may be best for you. How well any other treatment works will depend on your specific health problem.

More Facts

You have read (if a new patient) or re-read (if an established patient) the patient information sheet on sublingual allergy drop immunotherapy, and you understand it. Sublingual allergy drops are not approved by the Food and Drug Administration (FDA) and you are taking them as "off label" use for treatment of my environmental allergies. The allergen extracts are FDA approved for administration by injection. There is no guarantee has been made that this therapy will cure or resolve my symptoms.

SLIT should not be used if you have asthma that is uncontrolled. If you have sores in your mouth, your doctor may tell you not to use SLIT until your mouth is healed.

Your doctor should give you an emergency epinephrine pen (also called an EpiPen[®] auto-injector), in case you have an allergic reaction to SLIT. You should have this with you when you take your doses and you will be required to keep an up-to-date epinephrine pen throughout your treatment.

You cannot take beta-blockers (medications often prescribed for high blood pressure, heart conditions, and migraines) and allergy immunotherapy concurrently. This could be dangerous. If you are prescribed a beta-blocker in the future, you will need to immediately stop taking your allergy immunotherapy and call the office to notify the allergy staff.

The cost of the treatment is not covered by your health plan.

You may need to use SLIT for years. It is not yet clear if you must keep taking SLIT forever or if it can be stopped after several years. Missing doses of your SLIT may mean it will not work as well.

Allergy immunotherapy does not take the place of avoiding allergens that you are allergic (sensitized) to. The effectiveness of my treatment program depends on following recommendations about environmental controls and use of drugs.

While you are getting allergy immunotherapy drops, you must be assessed at least yearly by your prescribing doctor to determine if the therapy should be continued or changed.



Consent to Treatment

The first two (2) pages of this form told you the risks, likely results, other choices, and problems that could happen with sublingual immunotherapy. If, after you have read and reviewed this form with your doctor, you do not believe that you really understand the risks, likely results, other choices, and possible problems of sublingual immunotherapy, **do not sign the form until all your questions have been answered.**

I understand all the facts given to me in the first two (2) pages of this form. I give my consent to my prescribing doctor and his/her associates to give sublingual immunotherapy to me. By signing below, I agree that: my doctor has discussed all of the facts in this form with me, no one has given me a guarantee about success or outcome, I have had a chance to ask questions, and all of my questions have been answered.

By signing this form, I am expressing understanding of the billing policy. That is, once I decide to start or refill the sublingual immunotherapy treatment, I will be billed for the total number of doses made. The treatment will then be mixed in the doctor’s office only after payment is collected, usually several weeks in advance. The treatment vials can then be picked up at the office. Refills can be mailed overnight upon request, but I would be responsible for this charge.

Special Note: We cannot make any exceptions to the billing policy once this consent is signed.

Signature of Patient or Responsible Party

Date and Time

Relationship to Patient (if Responsible Party is not Patient)