



You have been recommended for Sublingual Immunotherapy by your Certified Allergy and Asthma Physician. Review the informational handouts and sign/return consent form if you are interested in starting Sublingual Immunotherapy. Please note that this form of treatment is not covered by insurance due to being considered “off label” usage. The cost to refill these vials monthly will be between \$125 and \$225. You will need to have an Epi-pen prescribed to you and bring your Epi-pen to your first appointment.

Sincerely,

Certified Allergy and Asthma Consultants

CERTIFIED ALLERGY & ASTHMA CONSULTANTS

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ORAL IMMUNOTHERAPY (ALLERGY DROPS) CONSENT

Patient's Name

Record No.

I have discussed the need for sublingual (under the tongue) allergy immunotherapy (allergy drops) with my Physician at our office visit as a treatment for my allergic condition. I understand the immunotherapy prescribed is comprised of allergy extracts also used for allergy injections and that sublingual use has not been approved by the Food and Drug Administration. This is known as an "off label" use. I received a patient information sheet describing reasons to stop sublingual allergy immunotherapy and to call the office. Alternate forms of treatment including allergy injections, the use of environmental control measures and allergen avoidance, and treatment with prescription medications were also discussed.

The potential side effects caused by sublingual allergy immunotherapy have been explained to me. I understand that they include, but are not limited to; itching of the mouth, lips or tongue, swelling under the tongue and throat irritation, and the possibility of a systemic reaction. A systemic reaction can vary from minor symptoms (itchy eyes, runny nose, sneezing) to a more severe reaction (wheezing, chest tightness, hives, difficulty swallowing). Although rare, patients may have more severe reactions, including drop in blood pressure, shock and even death.

The first dose of sublingual immunotherapy will be administered in the physician's office and I will be required to wait 30 minutes following administration. I may then be provided with additional doses to permit at-home administration. I understand to maximize the benefit from sublingual allergy immunotherapy that I must take it as prescribed. I understand that if I miss more than 7 consecutive doses, I need to contact the office for instructions before continuing treatment. I agree to report any generalized or systemic reactions immediately to the physician. An epinephrine auto injector has been prescribed and I have been trained on how to use it properly and understand when I need to use it.

I acknowledge that I am not presently taking a beta-blocker medication. I understand that these medications are commonly used to treat high blood pressure, arrhythmias, heart palpitations, tremors, glaucoma, and migraine headaches. They may increase my risk for a systemic reaction that is resistant to treatment. I agree to notify the physicians of this office if such a medication is prescribed to me.

In signing this consent, I acknowledge that I have read and understand the above information, the additional risk factors that may be present as described on the back, and the contents of the patient education brochure as well as the information sheet, and that my physician has satisfactorily answered my questions.

Patient's (Parent/Guardian) signature

Date

See reverse side for additional risk factors.

Additional Consent – Other Medical Conditions

Allergen Immunotherapy has a risk of allergic reactions as detailed on the previous page. Patients with certain medical conditions may be at greater risk of complications as a result of reactions from immunotherapy and/or treatment provided to care for these reactions if they were to occur.

Additional risks apply to me because of the presence of the following medical condition(s).

() Autoimmune conditions

Rheumatologic conditions, lupus, psoriasis, multiple sclerosis and others may be exacerbated as a result of allergen immunotherapy.

() Heart conditions

The presence of heart disease, irregular heart rhythm, and others carry greater risk of heart events including: sudden irregular rhythm, poor oxygen delivery, heart attack and cardiac arrest with resultant low blood pressure, low oxygen level and severe respiratory compromise from severe allergic reactions. Treatment with epinephrine used to reverse allergic reactions may also result in heart compromise, irregular rhythm, and poor outcome.

() Seizure disorder

Patients with seizure disorder are at risk of acute seizure events with drop in blood pressure and low oxygen level which may result from a severe allergic reaction. The combination of severe allergic reaction and acute seizure event can lead to greater risk of poor outcome from these reactions if they were to occur.

() Psychiatric conditions and Physical challenges

Patients with certain psychiatric conditions and physical challenges unable to communicate are at risk of delayed recognition of allergic reaction. This can lead to more severe reactions and complications if these reactions were to occur. The adverse effects of epinephrine may be potentiated in patients taking tricyclic antidepressants and monoamine oxidase inhibitors.

() Other _____

Patient Information Sheet: Sublingual Allergy Immunotherapy

Please contact the office and **stop** taking your sublingual (under-the-tongue) immunotherapy if any of the following occurs:

- **Missed Dose**

You forget to take your sublingual immunotherapy for more than 7 consecutive days.

- **Asthma**

Your asthma becomes uncontrolled, unstable, or severe (for example, Albuterol is required more than once in a 24-hour period and not for pre-treatment of exercise-induced symptoms). You are prescribed a new daily controller medication such as: Advair, Pulmicort, Symbicort, Dulera, Singulair, Flovent or QVAR by someone other than a Certified Allergy physician.

- **Dental Procedures or Sore Throat**

You develop oral lesions (such as mouth ulcers or cuts, infections, or thrush) or wounds (such as those following oral surgery or dental extraction). These can be worsened as a result of allergen immunotherapy.

- **Chest Pain or Swallowing Difficulty**

You experience severe or persistent chest pains or have trouble swallowing after starting allergen immunotherapy.

- **Eosinophilic Esophagitis (EoE)**

You are diagnosed with EoE, a relatively rare gastrointestinal condition, which can be made worse by oral immunotherapy.

- **Pregnancy**

You become pregnant.

- **Hypothyroidism**

You are diagnosed with hypothyroidism (under-active thyroid) and are instructed to take Synthroid (levothyroxine sodium). This medication may increase my risk for a systemic reaction to the medication.

- **Immunizations**

Do not use your allergy drops on the day you receive an immunization, such as the flu vaccine or a tetanus shot.



QUESTIONS AND ANSWERS ON SUBLINGUAL IMMUNOTHERAPY

WHAT IS SUBLINGUAL IMMUNOTHERAPY?

Sublingual immunotherapy, also known as “allergy drops”, is an alternative to traditional allergy injections (“allergy shots”). Like allergy injections, it is a natural, non-drug treatment for symptoms triggered by environmental allergens such as pollen, mold, dust mite, animal dander and stinging insects. It is specifically formulated for each patient using the same FDA approved allergens used in allergy injections. While the allergens used are FDA approved, their use in formulating allergy drops has not been approved by the FDA. This is known as an “off label” use of the allergens.

HOW DOES IT WORK?

Allergy drops are administered under the tongue and work like a vaccination by gradually decreasing your body’s abnormal or “allergic” immune response to typically harmless environmental allergens. By decreasing your sensitivity and increasing your tolerance upon exposure to these triggers, allergy symptoms are reduced.

HOW EFFECTIVE ARE ALLERGY DROPS?

Most clinical trials and surveys published over at least 20 years show that SLIT is relatively safe and effective for the treatment of nasal allergies, eye allergies, and asthma caused by dust mites, grass, ragweed, cat dander, and tree pollens. In 2013, the Agency for Healthcare Research and Quality (www.AHRQ.gov) concluded that there was sufficient evidence to support the overall effectiveness and safety of allergy drops for treating allergies and asthma. High quality studies directly comparing allergy drops and shots directly have not been performed, however most allergy experts agree that the available evidence supports the use of allergen injections over drops when possible.

WHO CAN BENEFIT FROM ALLERGY DROPS?

Patients with nasal symptoms, eye symptoms, sinus infections, or asthma triggered by environmental allergies may benefit from allergy drops. These conditions may include symptoms such as: runny nose, nasal congestion, post-nasal drip, sneezing, sinus infections, itchy/watery eyes, as well as coughing, wheezing, chest tightness or shortness of breath. Once the 3-5 year course of immunotherapy is complete, the majority of patients have long-lasting benefit with less of the daily hassle and costs of environmental controls and medications.

Patients suffering with allergy-induced asthma, one of the most common forms of asthma, have also been shown to have decreased asthma symptoms and need less asthma medications when incorporating allergy immunotherapy into their treatment regimen.

WHAT IS REQUIRED?

Because allergy drops work over time, they need to be taken regularly following the prescribed dosing schedule that accompanies the vial(s). Symptomatic benefit and decreased medication requirement are often seen within the first 3-6 months of initiating treatment.

WHAT ARE THE RISKS?

The only risk to allergy drops is a reaction to the drop itself. Symptoms may include: itching of the mouth, lips or tongue, swelling under the tongue and throat irritation, and the possibility of a systemic reaction. A systemic reaction can vary from minor symptoms (itchy eyes, runny nose, sneezing) to a more severe reaction (wheezing, chest tightness, hives, difficulty swallowing). Although very rare, patients may have more severe reactions, including drop in blood pressure, shock and even more rarely, death. When starting allergy drops, you will receive a prescription for an epinephrine auto injector and will be trained on its use, to treat any severe reaction while taking allergy drops.

SPECIAL SITUATIONS

Allergy drops should not be initiated while pregnant. Women who become pregnant during the course of treatment should contact our office for further recommendations.

Patients on beta blocker medications used to treat high blood pressure, arrhythmia, heart palpitations, tremors, glaucoma and migraine headaches may not be a candidate for allergen immunotherapy. Beta blocker medications may in some cases make it more difficult to treat a systemic reaction should it occur.

WHAT ABOUT COST?

The cost of allergy drops is not covered by insurance and is therefore the responsibility of the patient. The cost varies based upon the number of vials.

HOW DO I OBTAIN ALLERGY DROPS?

To obtain allergy drops, please contact our office at (518) 434-1446. We will ask that you sign a consent form for treatment and a formulation tailored to your specific allergies will be prepared by your physician. Our billing office will contact you to obtain payment and the drops will be prepared by our office. Following preparation, we'll contact you to come into the office for a meeting with a member of our nursing staff. The nurse will review your dosing schedule and teach you how to use an epinephrine auto injector, in the unlikely event you have a severe reaction to the drops.

Your initial set of vials will last 4 – 5 weeks. You will need to contact our office one week in advance to obtain refill vials.

If you have any questions that were not answered in this brochure or by your physician, please contact our office. A member of our clinical staff will be pleased to assist you.