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Questions and Answers About Oral Allergy Drops (Sublingual Immunotherapy or SLIT)

Why Allergen Immunotherapy?

Allergen Immunotherapy is a type of preventive treatment for allergens such as pollen, mold, dust mites, and animal danders. While medications such as antihistamines and nasal sprays only treat the symptoms, *Allergen immunotherapy treats the underlying cause of the allergic reaction* by inducing Immune tolerance to these antigens. It is done by administration of gradually increasing amounts of the specific antigens.

Why sublingual immunotherapy (SLIT)?

Until recently, the only way to successfully administer Allergen Immunotherapy in the United States was by injections (allergy shots) at the doctor's office. Sublingual immunotherapy is now being introduced in the United States and is an injection-free procedure that offers patients the freedom to treat their allergies conveniently in their own home.

What are some advantages of sublingual immunotherapy compared to traditional allergy injections?

There are numerous advantages of sublingual immunotherapy:

1. Main Advantage: No needles, No Injections, No Shots!
2. Much Less Risk of Systemic Anaphylactic Reaction, so that sublingual immunotherapy can be administered at home.
3. Time Savings: Treatment is administered once a day at home in a matter of minutes, eliminating the need for travel and wait in the doctor's office, and the mandatory 30 minute post injection observation period that is required after allergy injections. (Average: 60 minutes in Dr.'s Office + to and fro travel time)
4. For patients living a great distance from the doctor's office or for patients who travel frequently, sublingual immunotherapy offers the only way they can get Immunotherapy.

5. For working people (including full time moms) with very busy schedules, for children who cannot miss school or sports, for professionals who cannot miss work , and for anyone who just does not have the time to go sit in the doctor's office every week, this is the solution.

With so many obvious advantages why not everyone take sublingual immunotherapy instead of allergy injections? What are the disadvantages of SLIT?

There are several distinct disadvantages of sublingual immunotherapy:

1. **FDA “Off Label Use”:** Sublingual immunotherapy (SLIT) is FULLY APPROVED BY FDA for oral allergy tablets for Timothy Grass, Ragweed, Dustmite and Peanut powder. However, it is NOT approved for Allergy Drops (SLIT) that contain multiple allergens specifically designed for each patient after skin testing. Allergy Drops (SLIT) used in this manner has been used in Europe for many years and currently accounts for more than half of all immunotherapy administered in the European Union countries. As of now, FDA still considers this mode “investigational” and “off-label” in the United States. However, it is perfectly legal for a doctor to prescribe it and for a patient to take it as prescribed
2. **Financial:** *Since it is Off Label, most Health Insurance Plans in the US refuse to cover sublingual immunotherapy. Therefore the cost of allergy vaccine is fully borne by the patient.* So each patient needs to evaluate if for an equally effective treatment, the abovementioned advantages in terms of money value of time, convenience and the needle prick factor are worth the expense. Additionally, since it is a medically prescribed treatment for an illness the cost may be tax deductible under medical expenses and /or in a Health Savings Account (double check this with your tax advisor, please).

MEDICAID & MEDICARE DO NOT COVER OR PAY FOR Sublingual or Oral Allergy Drops. They cover Allergy vaccine only if it is given by injection.

3. **Only For Inhalants:** Sublingual immunotherapy has been shown to be as effective as Allergy Injections only for Inhalant Allergies. At present it is not recommended for Food Allergies, although this may change soon, as many studies are showing promise. SLIT is not recommended for Insect Sting allergies, Drug Allergies, Urticaria, or Contact Dermatitis Allergies (such as Poison Ivy Allergy)

How do I get started on sublingual Immunotherapy?

After your complete Allergy Evaluation if the treatment plan designed for you includes Inhalant Allergen Immunotherapy, your Health Care Provider will discuss injection and sublingual immunotherapy alternatives with you. Depending on the route you choose, appropriate allergy vaccine kit will be prepared for you, usually within one week. We will then need to see you in the office to answer all your questions, to have you sign the consent forms, to have you take the first dose in our presence, to observe you for at least a half an hour for any reactions, and to give you detailed instructions. If it is sublingual vaccine, you may then take your treatment vials with you for administration of daily doses at home. We will provide you with written dosing guidelines and renewal instructions and answer all your questions.

How quickly will I see relief of my allergy symptoms?

Although treatment success varies from patient to patient, we anticipate improvement within the first few months of treatment. Maximum benefit may take a year or so of regular therapy. Adjustments to your dosing may be made as the treatment progresses and the vaccine vials are renewed. We will expect you to keep us informed about how you are responding to the treatment. Of course, we will see you for periodic office visits on a regular basis.

Is there a minimum age for use of SLIT?

There are no age restrictions for sublingual immunotherapy, although it is rare to begin any form of immunotherapy prior to age five.

How will the dosing proceed?

There is an initial “build-up phase” that involves once-a-day dosing, beginning with a single drop from a lower concentration and gradually increasing the drop number and then the vaccine concentration over a period of 30 days. At the 30-day point, you will begin Maintenance dosing regimen with 5 drops as the Full Strength Vaccine. This 5 drop-per-day dose will be continued long term for control of your allergies as described below. We will need to see you in the office every three months at least thru the first year and then less often.

How will the drops be administered?

The allergy vaccines are provided in convenient Amber-Glass bottles with a pump dropper mechanism that dispenses accurate and exact drop size. Dosing should be done in the morning, preferably before breakfast. Rinse your mouth real well, open your mouth, lift your tongue so it touches the palate, then place the correct number of Drops under the tongue and hold it there for 2 to 3 minutes. There will be some salivation. Let the saliva spread the vaccine under the tongue. Resist the impulse to

swallow. A minimum period of two minutes of contact is necessary to ensure that the dendritic cells in the mucosa can firmly grab the antigens for transfer to the lymph nodes, where the immune system reacts with the antigens to produce tolerance. After two, preferably three minutes spit out the vaccine. Do not rinse mouth, eat or drink for 10 minutes. After that there is no restriction on rinsing, eating or drinking.

There is difference of opinion among experts on whether the vaccine should be swallowed or spat out. About 30% of the antigen dose in the vaccine is wasted by spitting out, theoretically slowing down the response. BUT, it is balanced by significant, almost total, reduction in risk of developing Eosinophilic Esophagitis, a major complication of oral allergy drops. We generally recommend the safer route of spitting, with full 3 mins of holding and 10 mins of not rinsing.

Do the drops have any taste?

Due to the glycerin in the extract, there may be a slight feeling of warmth and mild sweet taste as the glycerin mixes with the saliva. Since there are no taste buds under the tongue, most patients experience very little taste except when saliva makes it spread over the tongue.

How often and for how long will I need to take the drops?

The drops are taken once a day, every day, for 3-5 years. The daily dosing is not just for symptom control but to induce long term, long lasting immune tolerance to the antigens you are allergic to. So the dose is taken every day whether you have symptoms or not. Treatment duration varies from patient to patient, depending on the response to treatment and the need for continued symptom control. A minimum of three years is considered necessary to prevent relapse. We will review the need or

What if I forget to take the drops one day?

There is a dose adjustment schedule on the dosing guide sheet. In general, there will be no problem if you miss a day or two periodically. However, the best relief for your allergies will be experienced if you take the treatment each and every day. As with any preventive treatment, compliance is critical for success. The appropriate effective cumulative therapeutic doses are achieved only if daily therapy is maintained.

How long will a treatment set last?

The initial “build-up” treatment set will consist of three sequential increasing concentrations (three vials per set). You may either need one set; or two sets if the number of antigens is too many or they are the kind that cannot be mixed. Starting with the lowest concentration in each set you will build up the dosage as per

instructions with the bottles, and reach the full maintenance dose in approximately 30 days. The third bottle of each set is full concentration and will last you three weeks.

Thereafter, you will get maintenance treatment set, each will have 2 bottles, both containing maintenance concentrations, 160 drops in each bottle (5dx30days=150), enough for two months. If you are on two sets of vaccines due to too many allergies then you will get four bottles, two in each set. We will show and fully explain all this when the bottles are given to you These Refill Treatment sets will be prepared every two months.

Do I need to keep the vials refrigerated?

The treatment vials contain a glycerin preservative, which maintains stability at room temperature. However, most proteins are more stable in a refrigerator (NOT in a Freezer). You may keep the vial(s) you are currently using at room temperature, in a convenient location where you will not forget your dosing; and the other vials refrigerated to insure maximum potency.

Are there any medications that could interfere with my sublingual immunotherapy?

All kinds of immunotherapy, carries extra risk if you are taking a beta-blocker medication (usually used for high blood pressure, fast heartbeat, heart rhythm problems or glaucoma). Please inform your other doctors and pharmacist to warn you if any beta blocker containing drug is prescribed to you. If so, or if you are not sure what the medication is, please call our office and discuss before taking any more dose of the vaccine.

What are the potential side effects of sublingual immunotherapy?

Reported reactions to sublingual immunotherapy include itching of the tongue or lips (the most common reaction), gastrointestinal symptoms such as nausea and cramping, skin rashes including hives, and very rarely headaches. Systemic reactions (anaphylaxis) have been reported and may include symptoms such as throat tightness, wheezing, and a drop in blood pressure. These systemic reactions are extremely rare; there has never been a reported incidence of a fatal reaction to sublingual immunotherapy. However, you must always have an oral antihistamine available for mild local reactions, as well as an Epinephrine auto-injector (Epi-Pen®) available for systemic reactions. These precautionary measures will be discussed with you at the time sublingual immunotherapy is initiated.

How do I re-order my treatment set? Two weeks before the last date of your current vaccine set, you will need to complete the renewal order form and fax it to us (three weeks if you mail it). The renewal treatment set will be prepared only AFTER we

receive the ORDER Form along with PREPAYMENT for the order. Preparation of the vaccine takes one week. The vials may either be picked up or can be sent by mail

We Look Forward to Serving You.