

PATIENT INFORMATION ON IMMUNOTHERAPY (Allergy Shots) AND INFORMED CONSENT FOR TREATMENT- Dr. Michael Vaughn

1. Immunotherapy or “Allergy shots” have been proven beneficial for nasal allergies, asthma, eczema and stinging insect allergy and may also decrease the incidence of sinus infections. Allergy shots are typically offered only to allergic patients who have severe symptoms that affect their quality of life. Not all allergic patients need allergy shots for treatment of their symptoms. If however, medications and environmental changes are not sufficient to minimize symptoms, then allergy shots may be the only effective treatment option available. In persons who require multiple medications to control their symptoms, allergy shots may also be a cost saving option.

2. Immunotherapy works by gradually “turning off” allergy to plant pollens, molds, dust mites, animal dander and insect venom. During the “build-up” process, the allergen is usually injected ***two times each week*** in progressively stronger doses over a 6-month period until the “maintenance” vial is reached. After reaching the top recommended maintenance dose, the time between each injection can then be increased with the goal of making the maintenance shot interval ***twice per month***. In our office, 3-year course of allergy shots, given twice per month, typically results in a complete loss of allergen sensitivity however; an occasional patient may not be completely “cured” and require more than 3 years of treatment. Unfortunately, up to 50 % of patients who suffer from Allergic Rhinitis (AR), caused by allergic antibodies (IgE), also suffer with “Non-allergic Rhinitis” (NAR). NAR is caused by an unusual sensitivity to environmental irritants such as: tobacco smoke, perfumes, strong chemical odors, diesel fumes, spicy food, dust and many other irritants. Although the symptoms of NAR are similar to AR, NAR will not improve on allergy shots and NAR symptoms may require medications for control.

3. ***To obtain the best results, a patient needs to receive maintenance shots twice per month.*** Missing shots for more than one month may require a temporary dosage reduction, but missing shots for more than 6 weeks will typically necessitate a full re-start. Annual skin testing is recommended to judge the effectiveness of the shots since over time; skin testing reactions are expected to disappear. The results from each annual skin test are used to modify the doses of allergens contained in the shots (if necessary). The allergy shots are typically stopped when the skin testing is negative to the patient’s main allergy trigger(s) for more than 1 year.

4. **Immunotherapy injections may be associated with various types of side effects.** Side-effects are usually more common in the most severely allergic patients and also in those with asthma. The most common side effect is swelling and inflammation (tenderness) at the injection site. These “local” reactions almost always improve over time. Allergy shots may occasionally be associated with more serious generalized “systemic” reactions (**anaphylaxis**). Signs or symptoms of these reactions may consist of: itching away from the injection site, hives, body tissue swelling (distant from the injection site), asthma (new onset coughing, wheezing or chest tightness), abdominal pains, diarrhea, dizziness and even loss of consciousness. Although our office is prepared to treat any serious shot reaction that may develop, if the allergic symptoms do not respond quickly to our treatment, it may be necessary to transport you by EMS to the near-by Baptist or Methodist Hospital Emergency rooms for further monitoring.

5) **Data from large studies has revealed that most serious allergic reactions occurred within 30 minutes after an injection.** For this reason, all patients are required to remain on-site for 30 minutes after their allergy shot. In May 2015, we looked at the medical records from all allergy shots we administered in 2014.

We found that about 1 out of every 95 patients who received allergy shots developed a systemic allergic reaction (anaphylaxis). These reactions usually occurred following a shot administration from the 3rd or 4th vials. While these reactions were typically mild and reversed quickly with treatment, severe allergic reactions resulting in death have occurred following allergy shots. Because reactions can develop hours after a shot, every person receiving allergy shots is required to carry an epinephrine injector on the day of the injection (***we will not administer an allergy shot to anyone who is not carrying their EpiPen***). “Home” or self-administered allergy shots and “allergy drops”, offered by some non-Allergist physicians, are typically formulated using much lower concentrations of allergens than the “in-office” shots given by Allergists. As a result, these experimental treatments are less effective for symptom control than “full dose” allergy shots and will typically not cure allergic sensitivities. The FDA has approved oral immunotherapy tablets for only grass and ragweed.

6. **“RUSH” allergy shots are available at our office.** This treatment option is offered as a convenience to those who would otherwise have difficulty with the typical build-up schedule. With RUSH, 7 build-up injections are given in a three-hour session. In our clinical experience, “RUSH” treatment has been as safe as “conventional” treatment. In a 2004 medical record review, we found that among 255 patients who had completed “RUSH” with the first 2 build-up vials, only one allergic reaction occurred. RUSH is currently only available for the weakest allergen dilution vial. Although “RUSH” build-up can help reach the maintenance dose sooner, RUSH offers no long-term advantage over our “conventional” slower injection protocol and is simply a convenience option that reduces the number of office visits. We have found that when certain medications (antihistamines, Pepcid and Singulair) were given prior to allergen injections, these *“pre-meds”* reduced the frequency (and possibly the severity) of shot-induced allergic reactions and so we strongly recommend that all persons on allergy shots, even those choosing the “conventional” build-up protocol, take pre-meds on the day of an allergy shot.

7. **Fees for services:** Alamo Allergy and Asthma Associates charge a fee for mixing the bottles of allergy extract (we purchase our allergens from ALK – Abello). In addition, there is usually a shot administration fee each time an injection is given. (RUSH-allergy shots are typically billed as “time in our office” and you are not charged for each individual shot). Your insurance may require you to pay a co-pay each time you see us for medical care but there is no “office visit” charge for an allergy shot. ***Allergy shots are not scheduled;*** they are given on a walk-in basis as “first-come-first-served”. Although we are contracted with almost all insurance companies, coverage for allergy shot treatment varies. You are responsible for understanding the limitations of your plan. If your insurance benefits change during the process of receiving allergy shots, you are also responsible for immediately providing us with this updated information. If you choose to discontinue your allergy shots, there is no refund for any unused portion of the allergen mixture.

*** I am requesting to receive Immunotherapy (allergy shots) under the supervision of Alamo Asthma & Allergy Associates. I have read and understand the risks and benefits of allergy shots and all questions have been answered to my satisfaction.**

Patient Name _____

Date _____

Patient Signature _____

(Form revised 06/2015)