

The following information is for patients who may be considering immunotherapy (allergy shots or injections) as part of their allergy treatment plan.

The goal of immunotherapy is to reduce allergic sensitivities. Treatment involves a series of injections given on a regular weekly or bi-weekly basis. The kinds of allergy injections prescribed, as well as the number and frequency of the injections, will be described in a discussion with your doctor. The prescription is based on your particular symptoms, your examination and your test results.

Allergy injections are started at a low dosage. The strength and amount of the injections are gradually increased over a period of months, until you reach the highest dosage that has been prescribed by your doctor or a level above which there is a reaction. You'll then continue "maintenance" injections at this level. The best maintenance dosage for an individual is one that achieves relief of symptoms without unpleasant side effects.

Improvement of allergy symptoms will be gradual. About 85% to 90% of patients given allergy injections receive significant reduction in their allergic symptoms. However, improvements usually occur over a period of three to six months. The maximum benefit may not be reached until 12 to 24 months into treatment.

The duration of immunotherapy treatment varies greatly. The minimum treatment period for most patients is three to five years, but in many cases longer periods of treatment are beneficial or necessary. In general, the injections should be continued until about one year beyond the time when allergic symptoms have come under control. Thus, the total duration of treatment has to be individualized. The duration depends on the nature of the allergic problem, the rate and completeness of recovery, and whether symptoms return when immunotherapy is discontinued.

Because allergy injections are extracts of substances to which you are allergic, you and your doctor will need to be alert to any signs that you are having an allergic reaction to the injection. Early indications of a reaction are described in the accompanying *Immunotherapy: Frequently Asked Questions and Answers* and the *Consent for Administration of Allergy Injections*. You will be asked to read and sign the consent before beginning your immunotherapy. If you begin to develop local swelling (greater than two inches) at the injection site or have any other symptoms that you feel are due to the injection, *please contact us before your next injection* so that we may adjust the dosage.

Allergy injections should be given under the direct supervision of a physician, so that the physician can monitor potential problems and treat any reactions. If your injections are to be given somewhere other than in our office or clinic, we must have the name, address and telephone number of the physician who will assume the responsibility for administering your injections. We will provide you with a form to complete that will allow us to forward your extracts to another physician or medical facility. Allergenic extracts will be released **only to a licensed physician**.

After completing the initial series of injections, immunotherapy patients should have a follow-up visit. At that time, if your allergic symptoms are not clearly improving, the allergist-immunologist may make changes in your prescription to make it more effective for you. It is important for patients who are experiencing persistent allergic problems to have regular re-evaluations, usually at six- to 12-month intervals. Patients who are doing well, who are having no problems with their injections, and who have not developed any new medical problems should plan on a review of their treatment program with the doctor once a year.

You or a family member may be starting immunotherapy, sometimes called allergy shots. Patients frequently have questions about the injections. Many of the most common questions are addressed below. Please feel free to speak with one of our staff members if your questions are not satisfactorily answered, or if you have questions other than these. By working together, we will have the best opportunity for good results and improvement in your allergy symptoms.

What is immunotherapy?

Immunotherapy or allergy shots is a medical treatment involving a series of injections with gradually increasing doses of a vaccine or “extract” made from the allergens to which you are allergic.

Is every immunotherapy patient on the same prescription?

No. The allergy extract prescription is specifically designed for you, based on the results of an evaluation of your symptoms, medical history, physical findings and allergy testing. It is highly unlikely that two allergy patients will be on precisely the same extract prescription.

What conditions are treated with immunotherapy?

Immunotherapy is a preventive treatment for allergic respiratory conditions such as perennial and seasonal allergic rhinitis (“hay fever”), asthma (“wheezing”), and insect sting allergy.

What are the goals of immunotherapy?

The primary goal of immunotherapy is to relieve the symptoms caused by allergies. Immunotherapy should generally reduce your allergic sensitivities, thereby reducing symptoms and reducing the need for medications. Immunotherapy is *not* a cure for the condition, but it usually will improve many of the symptoms and complications of allergic disease.

How effective is immunotherapy?

Generally, 85% to 90% of patients who are receiving high-dose maintenance immunotherapy will have a significant reduction in their allergic symptoms, as well as a reduction in their need for additional medications.

What alternatives, in addition to immunotherapy, do I have for the treatment of my allergies?

Allergy problems are generally attacked from three directions: (1) avoidance of recognized allergens; (2) medications; and (3) immunotherapy. *Avoidance* of the offending allergen is the ideal solution and is usually recommended for allergens such as foods, drugs and animals. However, avoidance may be difficult when the allergen is airborne pollen or mold. *Medications* also may be beneficial, but only work with regular use and are most helpful when symptoms are mild. *Immunotherapy* is a “long-term” preventive treatment that can alter the causes of allergic symptoms.

It stimulates the patient’s immune defenses and is a natural response. A patient often will require a combination of avoidance measures, medications and immunotherapy for the most effective control.

Do I still have to avoid things to which I am allergic if I am getting allergy injections?

It always is wise to avoid known allergens, particularly easily avoided ones such as animals. However, many allergens such as pollen and mold are in the atmosphere and cannot be totally avoided. Allergy injections are especially useful for reducing reactions to these allergens. Very heavy exposure to an allergen may produce symptoms despite allergy injections. Common sense is the rule, and heavy exposures should be avoided whenever possible.

Should I take allergy medications while I am receiving injections?

There is no interference between allergy medications and allergy injections. As you begin your immunotherapy, you should continue your prescribed medications because immunotherapy will take time to become effective.

As you proceed toward “maintenance” immunotherapy, you may find that your need for allergy medications will decrease, and you will be able to gradually reduce or discontinue some of your medications. However, always talk with your physician before reducing an asthma medication.

How often will I get an allergy injection and how long until the injections begin to help my symptoms?

The “advancement phase” of your immunotherapy may take several months. The schedule of injections that your physician decides is best for you will determine when you reach maintenance levels. You should expect to begin seeing benefits from your immunotherapy as you reach maintenance levels, although some patients will require six to 12 months on high doses before seeing maximum benefit. Your dose should never be advanced if a significant reaction occurred after your last injection. Exceeding the optimal dose can lead to worsening of symptoms.

Why can't I give the injections to myself at home?

Allergy injections contain potent doses of allergens to which you are allergic. No matter how long you have been on allergy injections, the potential always exists for you to have a serious (and possibly even life-threatening) allergic reaction to the shot. Therefore, you must receive your injections in a physician's office where emergency treatment is immediately available. You may receive your injections in our office or in the office of another physician.

What types of reactions or side effects might result from an allergy injection?

Allergy shots *usually* cause no immediate problem. The only common side effect is localized swelling at the site of the injection, usually no larger than a quarter. Ice applied to the site of the swelling will help relieve some of the discomfort. There also are medications that may help avoid this side effect. Do not scratch or massage the injection site. Scratching may worsen the local reaction. You should *not* expect to have a major flare-up of your allergy symptoms after a shot. Notify us or the physician administering the injection immediately if you think you are having a reaction to an injection. Symptoms suggesting a reaction include:

- *any allergy symptom that occurs at a location other than the site of the injection*
- chest congestion or wheezing
- swelling of the tongue or throat
- itching at *any location*
- hives
- abdominal cramping
- light-headedness

These “anaphylactic” reactions must be treated promptly by the physician and staff. Most serious reactions begin within 20 to 30 minutes, while you are still under observation. However, *please do not ignore these generalized symptoms* even if they begin several hours after an injection. Return to our office or go to the nearest emergency room for treatment.

Do I have to remain in the physician's office for 20 or 30 minutes after every injection?

As noted above, there is *always* a slight risk that you could have a serious reaction to your allergy injection, no matter how long you have been on injections. Since serious reactions can be life-threatening, a physician should be readily available. If you do not have the time to wait after your injection, please do not come for your shot that day. It is better to come another day when you have the time to stay, so that we may administer your injection safely.

What are the reasons for postponing an allergy shot?

Call us before the immunotherapy appointment if you are ill or not feeling well—for example, a fever or wheezing within the past 12 hours. We may want to postpone your shot.

How often do I need to schedule a follow-up visit with the doctor?

The answer varies from patient to patient. You should check with your physician on how often you need to be seen.

When should I have allergy testing done again?

There is no need for allergy testing every year. The general recommendation is that you consider re-testing every three to five years, or as new problems seem to develop. The doctor can discuss possible re-testing at your annual visits.

Should I inform the allergist of new prescription medications from other doctors?

Yes! There are several medications, particularly some blood pressure medications known as “beta blockers” and ACE inhibitors, that usually are not given along with immunotherapy. Please notify the nurse of any new medications that have been prescribed for you since your last visit with the physician.

What if I become pregnant while on allergy shots?

Allergy injections are believed to be safe during pregnancy. The only possible harm to your baby could occur if you have a major reaction with a drop in blood pressure and a need for oxygen. We encourage conservative treatment during your pregnancy and not advancing your dose above the maximum dose given prior to pregnancy. The allergy injections will not cause or prevent allergies in your baby. Please arrange a follow-up visit if you become pregnant so your allergy treatment program can be reviewed. One of the benefits of continuing immunotherapy during pregnancy is that you may need less of other medications.

What should I do about my injections if I go on vacation?

You can skip injections while on vacation if you will be gone less than three weeks. Missing a week or two will not have a serious impact on the overall immunotherapy program. If you plan an extended trip, notify the office staff, and we will arrange for transfer of your extract to a local physician at your destination.

Will my final “maintenance dose” always remain the same volume and be given at the same interval?

No. As you reach “maintenance,” you may find that you can space your injections farther apart. If you have been receiving injections twice a week, your physician may suggest reducing them to once a week and observe for control of symptoms over the next month or two. If you continue to be well controlled, injections can be spaced every other week or up to four weeks apart. During peak pollen or mold seasons, you may notice that you are having more local reactions to your injections due to the increased allergen exposure in your surroundings. (This is called “co-seasonal” exposure). If this occurs, the maintenance volume will be temporarily reduced.

Immunotherapy

Consent for Administration of Allergy Injections

PLEASE READ AND BE CERTAIN THAT YOU UNDERSTAND THE FOLLOWING INFORMATION PRIOR TO SIGNING THIS CONSENT FOR TREATMENT

Purpose

The purpose of immunotherapy (allergy injections) is to decrease your sensitivity to allergy-causing substances, so that exposure to the offending allergens (pollen, mold, mites, insects, etc.) will result in fewer and less-severe symptoms. This does not mean that immunotherapy is a substitute for avoidance of known allergens or for allergy medications.

Indications

To qualify for immunotherapy, you must be allergic to one or more environmental substances that you cannot avoid. You may have hay fever or asthma that occurs upon exposure to suspected allergens, or you may have a history of severe reaction to an insect sting. Because of risks associated with immunotherapy, avoidance measures and medical management usually should be attempted first.

Efficacy

Improvement in your symptoms will not be immediate. It usually requires *three to six months* before any relief of allergy symptoms is noted, and it may take 12 to 24 months for full benefits to be evident. Usually 85% to 90% of allergic patients on immunotherapy note significant improvement of their symptoms. This means that symptoms are reduced, although not always eliminated.

Procedure

Allergy injections usually are begun at a very low dose. This dosage is gradually increased on a regular (usually weekly) basis until a therapeutic dose (often called the “maintenance dose”) is reached. The maintenance dose will differ from person to person. Injections typically are given once or twice a week while the allergen dose is being increased. This frequency reduces the chances of a reaction and permits the maintenance dose to be reached within a reasonable amount of time. After the maintenance dose is determined, the injections may be given every one to four weeks.

Duration of Treatment

It usually takes three to six months to reach a maintenance dose. The time may be longer if there are allergy shot reactions or if the injections are not received on a regular basis. For this reason, it is important that the recommended schedule of injections be followed. If you know that you cannot receive regular injections, immunotherapy should not be started. Allergy injections may be discontinued at the discretion of your physician if injections are frequently missed, as there is an increased risk of reactions under these circumstances. Most immunotherapy patients continue treatment for three to five years, after which the need for continuation is reassessed.

Adverse Reactions

Allergy injections are associated with some widely recognized risks. The risk is present because a substance to which you are known to be allergic is being injected into you. Some adverse reactions to allergy injections are potentially life-threatening and may require *immediate medical attention*. Here are brief descriptions of the kinds of possible reactions, listed in order of increasing severity:

A. Local Reactions

Local reactions are common and usually are restricted to a small area around the site of the injection.

However, they may involve the entire upper arm, with varying degrees of redness, swelling, pain and itching. These reactions are more likely to occur as you reach the higher concentrations and higher volume injections. The reactions may occur several hours after the injection. You should notify the nurse if your local reaction exceeds two inches in diameter or lasts until the following day.

B. Generalized Reactions

Generalized reactions occur rarely, but are the most important because of the potential danger of progression to low blood pressure and death if not treated. All generalized reactions require immediate evaluation and medical intervention. Generalized reactions may be of one or more types:

1. **Urticarial reactions (hives)** include rash, swelling and itch of more than one part of the body. There may be mild-to-moderate discomfort, primarily from the itching. This uncommon reaction may occur within minutes to hours after an injection.
2. **Angioedema** is swelling of any part of the body, inside or out, such as the ears, tongue, lips, throat, intestine, hands or feet, alone or in any combination. This occasionally may be accompanied by asthma or difficulty with breathing and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principal danger lies in suffocation resulting from swelling of the airway. Angioedema may occur within minutes after the injection and requires immediate medical attention.
3. **Anaphylactic shock** is acute asthma, vascular collapse (low blood pressure), unconsciousness and potentially death. This reaction usually occurs within minutes of the injection and is extremely rare.

The above generalized reactions are unpredictable and may occur with the first injection or after a long series of injections, with no previous warning. All generalized reactions require immediate evaluation and medical intervention. If a localized or generalized reaction occurs, the immunotherapy dosage will be adjusted. Appropriate advice and treatment will always be available from our office staff at the time of any adverse reaction.

Observation Period Following Injections

All patients receiving immunotherapy injections should wait in the physician's office **for 30 minutes after each injection**. If you have a reaction, you may be advised to remain longer for medical observation and treatment. If a generalized reaction occurs after you have left the physician's office, you should **immediately** return to the office or go to the nearest emergency medical facility. If you cannot wait the 30 minutes after your injection, you should not receive an immunotherapy injection.

There are several allergy shot-related deaths each year in the United States. Most generalized reactions are not life-threatening if treated promptly. You should wait in your doctor's office for the suggested observation time to be close to emergency treatment if needed. If you do not remain in the office for the designated time, your doctor may recommend that you discontinue immunotherapy.

Under no circumstances will injections be given without the immediate availability of emergency medical treatment. If the prescribed injections are to be given elsewhere, you must provide the name and address

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Consent for Administration of Allergy Injections

of the physician who will assume the responsibility for your injections. You will be asked to complete the “Request for Administration of Allergy Injections at an Outside Medical Facility.”

Pregnancy

Females of child-bearing potential: If you become pregnant while on immunotherapy, notify the office staff immediately so that the physician can determine an appropriate dosage schedule for the injections during pregnancy. Immunotherapy doses will *not* be advanced during pregnancy, but may be maintained at a constant level.

New Medications

Please notify the office staff if you start any new prescription medication, particularly medication for high blood pressure, migraine headaches or glaucoma. “Beta blocker” medications, often prescribed for heart diseases, are usually not allowed while on immunotherapy. Your injections may have to be discontinued if you take a beta blocker. Your physician will have to evaluate the risk/benefit in these circumstances.

If you have questions concerning anything in this consent for immunotherapy, please direct the questions to the nurses or to the physician. If you wish to begin immunotherapy, please sign the *Authorization for Treatment* (below).

Consent for Immunotherapy (Allergy Injections) Authorization for Treatment

I have read the information in this consent form and understand it. The opportunity has been provided for me to ask questions regarding the potential risks of immunotherapy, and these questions have been answered to my satisfaction. I understand that every precaution consistent with the best medical practice will be carried out to protect me from adverse reactions to immunotherapy. I do hereby give consent for the patient designated below to be given immunotherapy (allergy injections) over an extended period of time and at specified intervals, as prescribed. I hereby give authorization and consent for treatment by _____, M.D., and staff, including authorization and consent for treatment of any reactions that may occur as a result of an immunotherapy injection.

Printed Name of Immunotherapy Patient

Medical Record Number

Patient Signature (or Legal Guardian)

Date Signed

Witness

Date Signed

I certify that I have counseled this patient and/or authorized legal guardian concerning the information in this *Consent for Administration of Allergy Injections* and that it appears to me that the signee understands the nature, risks and benefits of the proposed treatment plan.

_____, M.D.

Date Signed

Immunotherapy

Request for Administration of Allergy Injections at an Outside Medical Facility

Please complete this form if the allergy extract will be administered at a medical facility other than the office of the allergist-immunologist.

I have read and signed the *Consent for Administration of Allergy Injections*. However, I wish to have my injections administered at the medical facility designated below, and I request that my extract vial(s), along with instructions for administration of the injections, be forwarded to the medical facility designated below. It is my responsibility to make certain that the facility and its staff are willing and able to provide allergy immunotherapy, and able to recognize and treat immediate or delayed adverse reactions that may result from the immunotherapy. I agree that I will not attempt to administer my extract injections to myself nor will I permit anyone who is not a licensed physician, or under the supervision of a licensed physician, to administer the extract injections. I further agree to notify this office if I transfer my immunotherapy extract vial(s) to any medical facility other than the one designated below. I understand that I may call this office at any time if questions or problems develop, and that I also may return at any time to this office for continued administration of my injections.

Printed Name of Immunotherapy Patient

Patient Signature (or Legal Guardian)

Date Signed

Witness

Date Signed

NAME, ADDRESS, AND PHONE NUMBER OF THE PHYSICIAN WHO WILL SUPERVISE THE ADMINISTRATION OF THE ALLERGY INJECTIONS:

Physician Name: _____

Street Address: _____

City/State/Zip: _____ Phone: _____

Approved:

_____, M.D.

Date Signed

Administration of Injections

1. Use a disposable allergy or tuberculin syringe with a 26-gauge or 27-gauge needle.
2. Observe sterile technique: follow appropriate OSHA guidelines.
3. Check vial for correct patient identification and dilution; shake vial before dose is withdrawn.
4. Ask the patient if there were any problems with the previous injection, then select dose accordingly.
5. Give injection subcutaneously (fatty tissue) in the back portion of the upper arm, four to six inches above the elbow.
6. After inserting the needle, gently aspirate for three seconds. If blood appears, discard the dose, draw a new dose, and select another site for the new injection. If no blood appears, proceed with the injection.
7. After the injection, have the patient apply pressure with a sterile gauze pad over the injection site for 60 seconds.
8. Alternate arms each time an injection is given.

Precautions

1. NEVER give an allergy injection unless AQUEOUS 1:1000 EPINEPHRINE and an extra syringe are readily available, along with other medications and equipment for treating systemic anaphylaxis. A PHYSICIAN MUST BE IMMEDIATELY AVAILABLE AT ALL TIMES WHEN INJECTIONS ARE GIVEN. THE ATTENDING PHYSICIAN SHOULD DIRECT RESUSCITATIVE MEASURES.
2. Do not give the injection if the patient is having acute wheezing, acute or severe allergy symptoms, or fever >99.5 degrees.
3. In patients with asthma, a pre-injection peak flow meter reading should be at least 80% of the patient's "personal best" reading.
4. The patient should not engage in vigorous exercise for one hour before and two hours after an allergy injection.
5. Do *not* administer allergy injections to a patient who is on a beta blocker medication unless a special exception has been made by the allergist-immunologist prescribing the allergy extract.
6. Notify our office if the patient becomes pregnant.
7. Keep antigen vials refrigerated, but not frozen.
8. ALL PATIENTS SHOULD BE OBSERVED FOR 20 TO 30 MINUTES AFTER EACH INJECTION.

If the Patient Has Missed an Injection

If the interval since the last injection is 15 to 21 days, repeat the last dose. If the interval since the last injection is 22 to 28 days, reduce the dose by 1/3 volume. If the interval since the last injection is 29 to 35 days, reduce the dose by 1/2 volume. If the interval is more than 35 days (five weeks), DO NOT TREAT. Call our office for further instructions.

Reactions to Allergy Injections

1. LOCAL REACTIONS

Treatment: Applying an ice pack to the injection site will usually relieve discomfort. An oral antihistamine also is indicated. An analgesic such as acetaminophen may be used.

Next Dose:	Reaction:	Response:
	(a) No reaction	(a) 'dose according to schedule
	(b) Induration <25 mm (1")	(b) 'dose according to schedule
	(c) Induration between 25-50 mm (1-2")	(c) Repeat last dose
	(d) Induration >50 mm (2")	(d) 'dose by at least 0.10 cc
	(e) Delayed reaction >50 mm (for longer than 24 hours)	(e) 'dose by at least 0.10 cc
	(f) Repeated local reactions >50 mm	(f) Have patient return to our office

2. SYSTEMIC REACTIONS

There is always the possibility of an allergic systemic reaction to one of the injections, even though the same dose may have been previously well tolerated. Anaphylactic symptoms may include itching (nose, throat, eyes, skin, palms of hands, soles of feet, etc.), sneezing, coughing, nasal congestion/drainage, throat tightness, wheezing, asthma or generalized hives. Rarely, hypotension and cardio-respiratory arrest may occur.

Treatment: At the first sign of any systemic reaction, give *at once* 0.25 cc of 1:1000 aqueous epinephrine in the opposite arm. Depending on the severity of the reaction and whether or not symptoms are interrupted, this dose may be repeated twice at 5-10 minute intervals. The dose should be adjusted by weight for young children. A tourniquet applied above the injection site will help slow absorption of the allergen. Every three minutes, the tourniquet should be loosened. A short-acting antihistamine should be given by mouth. An antihistamine can be given by injection for more severe reactions. Further emergency procedures should be at the discretion of the attending physician.

Next Dose: IF ANY SYSTEMIC REACTION HAS OCCURRED, HAVE THE PATIENT RETURN TO OUR OFFICE FOR FURTHER INSTRUCTIONS PRIOR TO GIVING ANY MORE ALLERGY INJECTIONS.

If you have any questions, do not hesitate to call our office.

The following is a summary of the position statement that was issued by the Committee on Practice Standards of the American Academy of Allergy, Asthma & Immunology in 1992.

Allergen immunotherapy should be administered only in settings where emergency equipment and trained personnel are immediately available to treat systemic anaphylactic reactions. The patient should be kept under observation for an appropriate period of time after any allergy injection, ordinarily 20 to 30 minutes. Personnel should be immediately available who have expertise in the following procedures: (1) Adjustment of the dose of allergenic extract for immunotherapy to minimize reaction; (2) Recognition and treatment of local reactions to allergenic extracts; (3) Recognition and treatment of systemic reactions to allergenic extracts; and (4) Basic cardiopulmonary resuscitation.

The following equipment and reagents should be readily available: (1) Stethoscope and sphygmo-manometer; (2) Tourniquets, syringes, hypodermic needles, and large-bore (14-gauge) needles; (3) Aqueous epinephrine HCl 1:1000; (4) Equipment for administering oxygen by mask or nasal cannula; (5) Equipment for administering intravenous saline solutions; (6) Oral airway; (7) Diphenhydramine or similar antihistamine for injection; (8) Aminophylline for intravenous administration; (9) Corticosteroids for intravenous administration; and (10) Vasopressor agents for intravenous administration. The proper use of these reagents and equipment by appropriately trained personnel should prove effective initial treatment for most, if not all, systemic reactions to allergenic extracts. The prompt recognition of systemic reactions and the immediate use of epinephrine are the mainstay of therapy.

There are several invasive procedures that are only rarely needed for treatment of systemic reactions. These include: (1) Direct laryngoscopy; (2) Direct current cardioversion (electrical counter-shock); (3) Tracheotomy; and (4) Intracardiac injection of drugs. The rare situation in which these procedures might be essential does not justify the risk of their being made available for use under less than ideal circumstances; therefore, it is neither necessary nor practical to insist that these procedures be immediately available to personnel using allergenic extracts.

Please note: It is important that the physician and staff who are administering immunotherapy be comfortable with the dosing of allergenic extracts, as well as with the recognition and treatment of systemic anaphylactic reactions. If any questions arise, please feel free to contact the physician's office.