

ADMINISTRATION OF VENOM IMMUNOTHERAPY (Venom Allergy Injections)

Please read and be certain that you understand the following information prior to signing the Venom Immunotherapy Patient Consent

PURPOSE

The purpose of venom immunotherapy (venom allergy injections) is to decrease your sensitivity to allergy causing venom so that exposure to the offending allergen (stinging insects) will result in fewer and less severe symptoms. This does not mean that immunotherapy is a substitute for avoidance of stinging insects or for the use of allergy medications, but rather is a supplement to those treatment measures. Epinephrine auto injector is needed to be carried at **all** times whether on venom immunotherapy or not.

Venom immunotherapy has been shown to lead to the formation of “blocking” or protective antibodies and a gradual decrease in allergic antibody levels. These changes may permit you to tolerate exposure to the allergen with fewer symptoms. You, in effect, become “immune” to the allergen.

INDICATIONS

To qualify for venom immunotherapy, there must be a documented history of a severe reaction to an insect sting in addition to a positive skin test or positive blood test.

EFFICACY

Approximately 90% or greater of allergic patients on venom immunotherapy note significant reduction in symptoms after a sting. This means that symptoms are reduced, although not always completely eliminated. **For this reason, epinephrine auto injector must be carried at all times – before, during and possibly after the course of venom immunotherapy.**

PROCEDURE

Venom immunotherapy contains the things you are allergic to and is usually begun at a very low dose. This vaccine dosage is gradually increased on a regular basis until a therapeutic dose (often called the “maintenance dose”) is reached. This frequency reduces the chances of a reaction and permits the maintenance dose to be reached within a reasonable amount of time. The maintenance dose may differ from person to person. After the maintenance dose is determined, the injections can usually be given every 4 to 6 weeks. Any time new maintenance venom is mixed, the dose given is

decreased and a minimum of three additional once weekly injections are required. This usually happens one to two times a year.

At times, venom rush therapy may be indicated. Rush therapy is an accelerated form of venom immunotherapy where multiple injections are administered at given intervals within an approximate two hour time period (if tolerated by the patient). Rush therapy can reduce the time it takes to reach your maintenance dose significantly. Venom rush therapy may be discontinued at the discretion of Dr. Edmondson or Dr. Hostetler at any given point if they feel it is necessary.

DURATION OF TREATMENT

It usually takes a minimum of 3 to 12 months to reach a maintenance dose. The time may be longer if there are reactions or if the injections are not received on a regular basis. For this reason, it is important that the recommended schedule be followed. **If you anticipate that regular injections cannot be maintained, immunotherapy should not be started.** Immunotherapy may be discontinued at the discretion of Dr. Edmondson or Dr. Hostetler if the injections are frequently missed, as there is an increased risk of reactions under these circumstances. All immunotherapy patients are required to have at least yearly follow-up with Dr. Edmondson or Dr. Hostetler.

ADVERSE REACTIONS

Immunotherapy is associated with some recognized risks. Risk is present because a substance to which you are known to be allergic is being injected into you. A few adverse reactions may be life-threatening and may require immediate medical attention. In order of increasing severity, the following brief descriptions explain the nature of these potential reactions:

A. LOCAL REACTIONS

Local reactions are common and are usually restricted to a small area around the site of the injection, however, they may involve a larger area, with varying degrees of redness, swelling, pain and itching. These reactions are more likely to occur as you reach the higher concentrations and higher volumes of vaccine. The reactions may occur several hours after the injection. You should notify medical personnel if your local reaction lasts more than 24 hours or is bothersome to you.

B. GENERALIZED REACTIONS

Generalized reactions occur rarely, but are the most important because of the potential danger of progression to loss of consciousness and death if not treated. These reactions may include:

1. **Urticarial reactions (hives)** include varying degrees of rash, swelling, and/or itching. 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 rare and is characterized by swelling of any part of the body, internally or externally; such as the ears, tongue, lips, throat, intestine, hands or feet, alone or in any combination. This may occasionally be accompanied by asthma and may progress to the most severe reaction, anaphylactic shock. In the absence of shock, the principle danger lies in suffocation due to swelling of the airway. Angioedema may occur within minutes after the injection and requires immediate medical attention.

3. **Asthma** may occur acutely with shortness of breath and wheezing. It may need immediate treatment to prevent acute respiratory distress.

4. **Anaphylactic shock** is the rarest complication, but is a serious event characterized by 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 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 generalized reaction occurs, the vaccine dosage will be adjusted for subsequent injections. Further venom injections will not be administered until a follow-up appointment with Dr. Edmondson or Dr. Hostetler is completed.

OBSERVATION PERIOD FOLLOWING INJECTIONS

All patients receiving immunotherapy injections are required to wait in the clinic area for **30 minutes following each injection.** If you have a reaction, you may be advised to remain in the clinic longer for medical observation and treatment. If a generalized reaction occurs after you have left the clinic area, you should **immediately return to the clinic 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. It is estimated that of the approximately 10 million allergy/venom injections administered each year in the United States there are several allergy/venom vaccine related deaths. While most systemic reactions are not life-threatening if treated promptly, this fact does stress the importance of remaining in the clinic for the suggested observation time. If you do not remain in the clinic area for the designated time, the doctor may recommend discontinuation of immunotherapy.

ADMINISTRATION OF IMMUNOTHERAPY AT AN OUTSIDE FACILITY

Under no circumstances will injections be permitted without the immediate availability of emergency medical treatment. If the prescribed injections are to be given elsewhere, our clinic must be provided with the name and address of the physician who will assume the responsibility for your injections. It is your responsibility to find the appropriate outside medical facility willing to administer your allergy injections. The provider of the outside medical facility is required to sign a consent. We must have this consent on file before your vaccine will be sent to the outside facility.

EXERCISE OR STRENUOUS ACTIVITY

No exercise or strenuous activities are allowed for one hour prior or two hours following injections.

PREGNANCY

Females of child-bearing potential: If you become pregnant while on venom immunotherapy, notify the office staff immediately so that Dr. Edmondson or Dr. Hostetler can determine an appropriate dosage schedule for the injections during pregnancy. Venom immunotherapy doses will not be advanced during pregnancy, but may be maintained at a constant level, and the interval of injections may be increased to monthly. Furthermore, venom immunotherapy will **never** be started during a pregnancy.

NEW MEDICATIONS

Please notify the medical staff if you start any new prescription medications, particularly medication for high blood pressure, migraine headaches, and glaucoma. Beta blocker medications are inadvisable while on immunotherapy, and your injections may need to be discontinued while you are taking a beta blocker.

ALLERGY INJECTION SCHEDULE

Allergy injections are offered in our office on a scheduled basis by appointment. A minimum 48 hour interval is necessary between injection visits. A parent or legal guardian must be present before an injection will be given to a minor. Children age 16 years and older may be allowed to receive their injections unaccompanied with signed permission from their parent or legal guardian.

In the event of a venom sting, **OCURRING ON THE DAY OF YOUR INJECTION**, no shots will be administered that day.

FINANCIAL POLICY

It is the patient's responsibility to provide up to date insurance information, and balances need to be current at the time of remixing serum. If you choose to discontinue allergy injections, you will still be responsible for any prior balances incurred.