



NORTH TEXAS ALLERGY & ASTHMA ASSOCIATES

TEXAS HEALTH RESOURCES DALLAS

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VENOM IMMUNOTHERAPY PACKET

Dear Patient,

In effort to ensure that you are receiving the optimal therapy for your allergy injections; we have put together a packet for you.

This packet includes:

1. What are allergy shots (immunotherapy)?
2. Immunotherapy policies and procedures
3. Beta – Blocker warning page
4. Sample schedule of antigen desensitization
5. **Informed consent for immunotherapy (please sign)**
6. Clinical indications for hymenoptera and/or fire ant immunotherapy

If you have any questions regarding the information provided please contact our office at the information above. Thank you.

Sincerely yours,

North Texas Allergy & Asthma Associates

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VENOM IMMUNOTHERAPY

What is stinging insect immunotherapy?

Venom immunotherapy (VIT) is recommended for all patients who have experienced a systemic reaction to an insect sting and who have specific IgE to venom allergens shown either by skin or blood test. Individuals with a history of a systemic reaction to an insect sting are at increased risk of subsequent systemic sting reactions. This risk can be significantly reduced with immunotherapy.

What are the benefits of allergy injections?

- VIT reduces the risk of systemic reactions when re-stung in stinging insect-sensitive patient from up to 60% to 3%.
- Evidence suggests that 80-90% of patients will not have a systemic reaction to an insect sting if VIT is stopped after 3-5 yrs.
- It may alleviate anxiety related to insect stings.

What are the drawbacks or risks of allergy injections?

- Anaphylaxis (severe allergic reaction) from receiving immunotherapy
- Not a "quick fix"
- May not be covered fully by all insurance companies
- Requires frequent visits to reach standard effective dose
- Still requires patient to continue carrying epi-pen

How are injections given and for how long?

Typically allergy injections are given once a week until a predetermined target or "maintenance" dose is achieved. This usually takes about 6 months (approximately 24 injections). Injections are usually continued for 3-5 years of maintenance therapy. At that time, you and your doctor will make a decision about whether to gradually taper your shots or to continue the injections longer.

What are common reactions to immunotherapy?

Local reactions (swelling, itching or tenderness at the injection site) may occur in some patients and usually subside in a day or less. Large local reactions and generalized (systemic) reactions may occur in 1-5 % of patients receiving allergy injections and usually occur in the build up phase, although they can occur at anytime during the course of the treatment. These reactions necessitate a dosage adjustment. Generalized reactions may consist of any or all of the following symptoms:

- Hives, itchy eyes, nose or throat, runny nose, nasal congestion, sneezing
- Tightness in the chest and or throat, coughing and or wheezing
- Nauseas and vomiting, abdominal cramps
- Lightheadedness or faintness and sometimes shock

How do we treat reactions?

Simple local reactions that consist of: swelling of the arm, redness or tenderness at the site of the injection are best handled with simple measures such as local cold compress or use of medications such as an antihistamine. For systemic reactions adrenaline (epinephrine) is usually given to counteract the reaction. Severe reactions are treated with various methods and may include hospitalizations or emergency room visits. If you experience a generalized reaction after leaving our office, please return to the office or proceed to the nearest emergency room (ER).



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IMMUNOTHERAPY POLICIES & PROCEDURES

Injection Administration Instructions:

1. Injections are to be recorded by dose, date, reactions and location.
2. Prior to each injection an inquiry will be made regarding reactions to previous injections and general state of health. Periodically check medications that might contraindicate immunotherapy (beta-blockers) and make sure patients are aware of the beta-blocker warning.
3. Treatment should be initiated at the dilution from the physician's orders at a dosage of 0.05 cc. At regular intervals the dosage and dilution will be increased. Build-up treatment is administered at typically once a week in accordance with the scheduled dosage.
4. Most patients will reach a maintenance dose of 1 cc of the undiluted vial. If doing well after 6 weeks of weekly maintenance dose injections, patients can try to increase the interval of their injections to every 2 weeks. Patients, who have been on maintenance dose injections every 2 weeks for 6 weeks and are doing well, may receive their maintenance injections every 3 weeks. Patients, who have been on maintenance injections every 3 weeks for 6 weeks and are doing well, may take maintenance injections every 4 weeks (monthly) and stay at this injection interval.
5. All patients must remain under observation for 20-30 minutes following injections to observe and then record local or generalized reactions (severe reactions commonly begin within this period of time).
6. Venom immunotherapy must be administered by trained technicians or nursing staff, with a physician in attendance. Unusual reactions to immunotherapy or modifications from the regime described above needs to be discussed with the physician.
7. Each bottle contains more than the amount called for by the schedule. This is to cover any wastage or added doses that may be required.

Recommended Technique for Immunotherapy

1. Antigens should be stored under refrigeration at a temperature 37°F to 43°F.
2. A separate disposable tuberculin syringe and needle must be used for each injection.
3. Extract should not be given superficially (intradermal) as it will cause burning and we suggest you apply pressure with cotton after the injection is given to prevent leakage.
4. Injections should be given **subcutaneously** in the outer aspect of the upper arm, midway between the shoulder and elbow. Avoid blood vessels and be sure to draw back to ensure that you are not in a blood vessel before administering the injection. Alternate arms are used for the series of injections. Do not massage the area.
5. Prior to each injection an inquiry should be made regarding delayed or immediate reactions following the last injections and also the patient's present state of health. If any questions arise as to the advisability of an injection, withhold it and consult with this office or physician.
6. An emergency kit with adrenaline (1:1000), IV fluids, tourniquet, steroids, antihistamine, oxygen, etc. should be readily available to treat systemic reactions.
7. To avoid potential serious reactions, error on the conservative side of therapy, when a question arises, contact the allergist at our office.
8. For those with asthma or breathing problems, a spirometry or peak flow should be performed before giving the injections to ensure that the patient is not having breathing difficulties. For patients in the build-up, spirometry or peak flow can be done weekly unless his/her condition dictates it should be done more frequently.

What to do if you miss an injection?

There have been no studies that have investigated the effect of dosage modification for gaps in immunotherapy injection intervals. Below is a suggested approach to modification of doses of allergen immunotherapy because of gaps between treatment during the build-up and maintenance phase

Build-up phase (time intervals from last injection). **Day 0 = time from last injection**

- 0 to 14 days, continue as scheduled
- 15 to 20 days, reduce by 1 dose.
- 21 to 28 days, reduce by 2 doses.
- 29 to 35 days, reduce by 4 doses
- >36 days, contact physician for orders

Then increase the dose for each injection as directed on the immunotherapy schedule until therapeutic maintenance dose is reached.

Maintenance phase (remember time intervals can be at 2, 3, or 4 week intervals based on the patient's maintenance schedule). **Day 0 = time from missed scheduled injection (for example if shots are every 14 days then day 0 starts at day 14 from last injection).**

- 0 to 7 days, repeat last dose.
- 8 to 15 days, reduce dose by 2 doses.
- 16 to 24 days, reduce dose by 4 doses.
- >25 days, contact physician for orders.

Then increase the dose for each injection visit as directed on the immunotherapy schedule until therapeutic maintenance dose is reached. Then the patient can work-up to their regularly scheduled maintenance interval as above (i.e to injections every 2 to 4 weeks).

Local reactions

Management of local reactions: recent literature suggests that individual local reactions do not predict systemic reactions. However, one study found that the rate of large local reactions, defined as ≥ 25 mm was almost 4 times higher (35.2% vs 8.9% of all visits and 19.5% vs 5.3% of all injections; $P < .001$ for each) among patients who subsequently experienced a systemic reaction compared with those who had never experienced a systemic reaction. For patient comfort dosage adjustments should be considered if large local reactions develop.

Guidelines for administration of allergy injection based on reaction size

- Negative: Swelling (as in a welt NOT the redness) <25 mm (quarter size) - progress according to schedule.
- Swelling 26-40 mm (quarter to golf ball size) – repeat same dose
- Swelling persisting more than 24 hours or over 40 mm (larger than golf ball) - return to the last dosage which caused no reaction.

If reduced dose is tolerated, increase dose each injection visit as directed on the immunotherapy schedule until therapeutic maintenance dose is reached. If local reactions persist, patient should be seen in our office with dosage sheet or contact the allergist at our office.

Systemic Reactions

A systemic or constitutional reaction usually occurs within 20-30 minutes and may consist of an increase in the allergic symptoms for which the injections are being given. In addition hypotension, respiratory, cardiovascular, GI or GU symptoms, flushing, hives or CNS symptoms may occur. If a patient feels any of these symptoms, they should immediately let the technician know so that adrenalin (epinephrine) or other medications may be administered under physicians order. These systemic reactions generally occur within the 20 minute waiting period, but rarely there may be delayed reactions occurring 30 minutes to 18 hours after the injection. If a delayed reaction occurs, it is imperative that the patient inform the allergy technician prior to the next injection. All systemic reactions should be reported to this office so that further recommendations regarding immunotherapy may be made.

If any questions should arise which are not answered or explained fully in the above statements, please contact our office as we are here to help in any and every way possible. For full detailed information, please refer to the Immunotherapy: Practice Parameters published by the Joint Council of Allergy, Asthma, and Immunology (JCAAI).

Additional Considerations:

Refrigeration: If vaccine is exposed to extreme heat or cold or if serum becomes cloudy, do not administer and notify the office.

Expiration date: Allergen vaccines have an expiration date and should be replaced after this date.

Pregnant: If the patient becomes pregnant, do not administer any further injections. Have her schedule an appointment with our office and bring vials and all dosage sheets for this visit.

Wheezing: do not give allergy shots if the patient is having asthma symptoms.

Asthmatic patients: Peak flow measurements or another form of breathing test should be done prior to all injections if indicated or if patient is symptomatic. If the peak flow measurement is **less than 70%** of the patient's baseline, the allergy injection should **not be given until the patient is further evaluated by physician.**

Exercise: **No exercise** for at least **4 hours** after receiving allergy injection.



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IMPORTANT WARNING

Please tell us if you are taking a **BETA BLOCKER** since this class of drug may be dangerous in combination with allergy injections or skin testing. Beta Blockers are medications used in a variety of disorders, including hypertension (high blood pressure), heart disease, glaucoma, headaches and many more.

Individual medications containing beta-blockers (examples include but are but not limited to):

<u>Brand Name</u>	<u>Generic Name</u>
Coreg	Carvedilol
Normodyne	Ladetalol
Trandate	Labetalol
Cartrol	Carteolol
Levatol	Penbutolol
Sectral	Acebutolol
Visken	Pindolol
Betachron E-R	Propranolol
Blocadren	Timolol
Corgard	Nadolol
Inderal	Propranolol
Innopran XL	Propranolol
Kerlone	Betaxolol
Lopressor	Metoprolol
Tenormin	Atenolol
Toprol XL	Metoprolol
Zebeta	Bisoprolol

Combination medications containing beta-blockers (examples include but are but not limited to):

<u>Brand Name</u>	<u>Generic Name</u>
Corzide	Nadolol + bendroflumethiazide
Inderide	Propranolol + hydrochlorothiazide
Lopressor HCT	Metoprolol + hydrochlorothiazide
Timolide	Timolol + hydrochlorothiazide
Tenoretic	Atenolol + chlorthalidone
Ziac	Bisoprolol + hydrochlorothiazide

Eye drops containing beta-blockers (examples include but are but not limited to):

<u>Brand Name</u>	<u>Generic Name</u>
Akbeta or Betagan Liquifilm	Levobunolol
Betopics S Ophthalmic Suspension	Betaxolol
Ocupress	Carteolol Hydrochloride
Betaxon	Levobetaxolol
Timoptic or Timoptix XE or Betimol	Timolol
Optipranolol	Metipranolol
CoSopt	



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SAMPLE SCHEDULE OF HYMENOPTERA VENOM DESENSITIZATION*

Dose/Injection**	Vial Color	Amount Injected	Number of Lines on Syringe***	Dose (mcg/ml)
1	Green	0.05 cc	(5 lines)	0.1
2	Green	0.10 cc	(10 lines)	0.1
3	Green	0.20 cc	(20 lines)	0.1
4	Green	0.30 cc	(30 lines)	0.1
5	Green	0.40 cc	(40 lines)	0.1
6	Blue	0.05 cc	(5 lines)	1
7	Blue	0.10 cc	(10 lines)	1
8	Blue	0.20 cc	(20 lines)	1
9	Blue	0.30 cc	(30 lines)	1
10	Blue	0.40 cc	(40 lines)	1
11	Yellow	0.05 cc	(5 lines)	10
12	Yellow	0.10 cc	(10 lines)	10
13	Yellow	0.20 cc	(20 lines)	10
14	Yellow	0.30 cc	(30 lines)	10
15	Yellow	0.40 cc	(40 lines)	10
16	Yellow	0.50 cc	(50 lines)	10
17	Silver	0.05 cc	(5 lines)	100
18	Silver	0.10 cc	(10 lines)	100
19	Silver	0.20 cc	(20 lines)	100
20	Silver	0.30 cc	(30 lines)	100
21	Silver	0.40 cc	(40 lines)	100
22	Silver	0.60 cc	(50 lines)	100
23	Silver	0.80 cc	(80 lines)	100
24 & Beyond	Silver	1 cc	(100 lines)	100

Notes:

*The chart above represents a sample dosage schedule for a typical patient. Actual dose/injection will vary based on an individual's reactions and number/schedule of visits. Please refer to "Immunotherapy Policies & Procedures" sheets for more instructions.

** Dose/injection 1-22 represent the "Build-up" phase of immunotherapy. Dose 23 & beyond represents the "Maintenance" dose and will be continued for the length of time that immunotherapy is performed.

*** Based on BD Allergy Syringe (1 ml 27G ½") – Ref 305540



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SAMPLE SCHEDULE OF FIRE ANT VENOM DESENSITIZATION*

Dose/Injection**	Vial Color	Amount Injected	Number of Lines on Syringe***	Concentration (wt / vol)
1	Green	0.05 cc	(5 lines)	1:100,000
2	Green	0.10 cc	(10 lines)	1:100,000
3	Green	0.20 cc	(20 lines)	1:100,000
4	Green	0.30 cc	(30 lines)	1:100,000
5	Green	0.40 cc	(40 lines)	1:100,000
6	Blue	0.05 cc	(5 lines)	1: 10,000
7	Blue	0.10 cc	(10 lines)	1: 10,000
8	Blue	0.20 cc	(20 lines)	1: 10,000
9	Blue	0.30 cc	(30 lines)	1: 10,000
10	Blue	0.40 cc	(40 lines)	1: 10,000
11	Yellow	0.05 cc	(5 lines)	1:1000
12	Yellow	0.10 cc	(10 lines)	1:1000
13	Yellow	0.20 cc	(20 lines)	1:1000
14	Yellow	0.30 cc	(30 lines)	1:1000
15	Yellow	0.40 cc	(40 lines)	1:1000
16	Yellow	0.50 cc	(50 lines)	1:1000
17	Silver	0.05 cc	(5 lines)	1:100
18	Silver	0.10 cc	(10 lines)	1:100
19	Silver	0.15 cc	(20 lines)	1:100
20	Silver	0.20 cc	(30 lines)	1:100
21	Silver	0.25 cc	(40 lines)	1:100
22	Silver	0.30 cc	(50 lines)	1:100
23	Silver	0.40 cc	(80 lines)	1:100
24 & Beyond	Silver	0.50 cc	(100 lines)	1:100

Notes:

*The chart above represents a sample dosage schedule for a typical patient. Actual dose/injection will vary based on an individual's reactions and number/schedule of visits. Please refer to "Immunotherapy Policies & Procedures" sheets for more instructions.

** Dose/injection 1-22 represent the "Build-up" phase of immunotherapy. Dose 23 & beyond represents the "Maintenance" dose and will be continued for the length of time that immunotherapy is performed.

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INFORMED CONSENT FOR IMMUNOTHERAPY

I (we) request North Texas Allergy & Asthma Associates and/or my primary care doctor to administer the allergy immunotherapy program ("immunotherapy") also known as allergy shots.

I (we) understand that immunotherapy may result in complications of anaphylaxis and even death. The American Academy of Allergy, Asthma, and Immunology recommends that immunotherapy be given under a physician's supervision. This practice believes this position is medically appropriate and that you should always obtain your injection by trained personnel, either in our office or another medical setting. Thus, I (we) understand that the immunotherapy is to be administered under a physician's supervision.

Furthermore, I (we) understand that it is required for me to wait in the waiting room **AT LEAST 20 MINUTES** after each allergy injection. If I (we) leave early, I (we) understand that it is against medical advice and will hold my treating physician and North Texas Allergy & Asthma Associates and their staff free of any liability.

In the event that I (we) receive immunotherapy, I (we) will notify the doctor or staff immediately if I (we) have any allergic reactions to my injections so that proper treatment can be initiated. I (we) understand that any time immunotherapy is given; there is a rare chance of nicking a tiny blood vessel causing a bruise, numbness or pain. If swelling is over 2 inches at the site of injection, I (we) will notify the nurse or physician before receiving my next injection.

I (we) understand that as a patient taking immunotherapy, I (we) should not use Beta-Blockers because of the inability to treat an allergic reaction, including hypotension or shock. I (we) also understand that while taking immunotherapy I (we) should not use MAO Inhibitors drugs for depression unless specifically approved by my treating physician at North Texas Allergy & Asthma Associates since such drugs may cause high blood pressure when adrenalin or other prescription medications are administered.

I (we) have been given the opportunity to ask questions about my condition and treatment, alternative forms of treatment, the procedures to be used, and the risks and hazards involved, I (we) believe that I (we) have sufficient information to give this informed consent. I (we) acknowledge that this disclosure and informed consent has been fully explained to me, that I (we) have read it or have had it read to me and I (we) understand its contents.

Date: _____

Patient Signature: _____

Patient Name: _____

Address: _____

If minor, Name of Legal Guardian: _____

Signature of Legal Guardian: _____



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CLINICAL INDICATIONS FOR ALLERGEN IMMUNOTHERAPY

Date: _____

Patient's Name: _____

In patients with reactions to hymenoptera sting:

- _____ Any age: history of a systemic reaction to a hymenoptera sting (especially if the reaction was associated with respiratory or cardiovascular symptoms) and demonstrable evidence of clinically relevant specific IgE antibodies.
- _____ Age: Over 16 years: History of a systemic reaction limited to the skin, and demonstrable evidence of clinically relevant specific IgE antibodies.
- _____ History of a systemic reaction to imported fire ant and demonstrable evidence of clinically relevant specific IgE antibodies.

Patients younger than 16 years who present with a history of only cutaneous symptoms to hymenoptera stings may not require immunotherapy. If immunotherapy is required, comments are necessary.

Comments: _____
