STANDARDIZED BERMUDA GRASS POLLEN- cynodon dactylon pollen injection, solution
STANDARDIZED KENTUCKY BLUEGRASS POLLEN- poa pratensis pollen injection, solution
STANDARDIZED MEADOW FESCUE GRASS POLLEN- festuca elatior pollen injection, solution
STANDARDIZED ORCHARD GRASS POLLEN- dactylis glomerata pollen injection, solution
STANDARDIZED REDTOP GRASS POLLEN- agrostis alba pollen injection, solution
STANDARDIZED PERENNIAL RYEGRASS GRASS POLLEN- lolium perenne pollen injection, solution
STANDARDIZED SWEET VERNAL GRASS POLLEN- anthoxanthum odoratum pollen injection, solution
STANDARDIZED TIMOTHY GRASS POLLEN- phleum pratense pollen injection, solution
Allergy Laboratories, Inc.

Standardized Grasses

ALLERGY LABORATORIES, INC.
Oklahoma City OK 73109

INSTRUCTIONS AND DOSAGE SCHEDULE FOR
STANDARDIZED ALLERGENIC EXTRACTS

BERMUDA GRASS POLLEN *(Cynodon dactylon)*

KENTUCKY BLUE GRASS POLLEN *(Poa pratensis)*

MEADOW FESCUE POLLEN *(Festuca elatior)*

ORCHARD GRASS POLLEN *(Dactylis glomerata)*

REDTOP GRASS POLLEN *(Agrostis alba)*

PERENNIAL RYE GRASS POLLEN *(Lolium perenne)*

SWEET VERNAL GRASS POLLEN *(Anthoxanthum odoratum)*

TIMOTHY GRASS POLLEN *(Phleum pratense)*

WARNING

This product is intended for use by physicians who are experienced in the administration of allergenic extracts and the emergency care of anaphylaxis or for use under the guidance of an allergy specialist.

STANDARDIZED GRASS POLLEN EXTRACTS LABELED IN BAU/ml ARE NOT INTERCHANGEABLE WITH GRASS POLLEN EXTRACTS LABELED IN AU/ml OR WITH NON-STANDARDIZED (WEIGHT/VOLUME) GRASS POLLEN EXTRACTS. For guidance in selecting dose, refer to Table A in the Clinical Pharmacology section that describes the potency of non-standardized grass pollen extracts. Comparative skin tests can be performed to determine the relative potency before initial use of new extracts. For previously untreated patents, initial dose must be based on skin testing as described in the Dosage and Administration section of this insert. Patients being switched from other types of extracts to Allergy Laboratories should have their dose adjusted. Extracts standardized in BAU (Bioequivalent Allergy Unit) may differ in potency from non-standardized extracts. Comparative skin tests can be performed to determine relative potency of standardized versus non-standardized extracts. The dosage should be reduced 75% when switching from one lot of standardized grass pollen extract to another Iot. Patients with unstable or severe asthma, including steroid-dependent asthma, are at increased risk for more frequent and more severe reactions from allergy extract injections. Greater caution must be exerted with such patients at all phases of extract administration, but particularly during build up. For example, extract therapy might be initiated at weaker concentrations and built by smaller dosage increments than in comparably allergic rhinitis patients without asthma. Also when asthma is poorly controlled, the injection regimen might be temporarily interrupted (at the discretion of the physician) until control of asthma is re-established. Whenever a reaction occurs in such patients their asthma should be medically stabilized before injections are resumed with an appropriate dosage reduction. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact physician's office if reaction symptoms occur. **As with all allergenic extracts, severe systemic reactions may occur. In certain individuals these life threatening reactions may be fatal.** Patients should be observed for at least 30 minutes following treatment and emergency measures as well as personnel trained in their use should be immediately available in the event of a life threatening reaction. Serious adverse reactions can be reported to the U S Food and Drug Administration MedWatch Program. The MedWatch forms can be obtained by calling 1-800-FDA-1088. The address is MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

This product should not be injected intravenously. Subcutaneous injections are recommended.

Patients who are taking non-selective beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. Refer also to the warnings, precautions, adverse reactions and dosage sections below.

DESCRIPTION:

Standardized grass pollen extracts labeled in BAU/ml are not interchangeable with grass pollen extracts labeled in AU/ml or with non-standardized grass pollen extracts. The recommended route of administration for immunotherapy is subcutaneous. The routes of administration for diagnostic purposes are intradermal or prick-puncture of the skin. Do not inject intravenously. The extract is sterile and contains 50% (v/v) glycerin as a preservative. Standardized grass pollen extracts are available in both 10,000 BAU/ml and 100,000 BAU/ml potencies, except for Bermuda which is only available in 10,000 BAU/ml. The source material of the standardized grass extracts are the grass pollens. The 100,000 BAU/ml grass pollen extracts are prepared by extracting pollen at a 1:10 w/v ratio then diluting if necessary to the appropriate range for 100,000 BAU/ml. The 10,000 BAU/ml grass pollen extracts are

prepared by dilution of the 100,000 BAU/ml grass pollen extracts. The 10,000 BAU/ml Bermuda grass pollen extract is prepared by extracting Bermuda grass pollen at a 1:10 w/v ratio then diluting if necessary to the appropriate range for 10,000 BAU/ml.

The potency (in Bioequivalent Allergy Units per ml or BAU/ml) of standardized grass pollen extracts is determined by an in-vitro ELISA Competition assay (1) against CBER reference extracts and CBER reference serum pools distributed by the Center for Biologics Evaluation and Research, U S Food and Drug Administration. Potency based on Bioequivalent Allergy Units (BAU/ml) is printed on the label. FDA reference grass pollen extracts were assigned potency designations based on quantitative skin testing (2). The FDA reference extracts which can be diluted 1:500,000 fold intradermally to produce a sum of erythema diameter response of 50mm in highly puncture reactive subjects have been assigned 10,000 BAU/ml. References which can be diluted 1:5,000,000 fold intraderrnally to produce a sum of erythema diameter response of 50mm have been assigned 100,000 BAU/ml.

INACTIVE INGREDIENTS:

Glycerinated extracts contain:

glycerin	50.0 % v/v
sodium chloride	0.166 % w/v
sodium bicarbonate	0.091 % w/v

CLINICAL PHARMACOLOGY:

The allergic state is initiated by an immune response inducing B cells to produce IgE antibodies to specific allergens. IgE antibodies bind to surface receptors on mast cells and basophils. When antigens gain access to the immune system they react with the bound IgE. The reacting antigen to the surface bound IgE stimulates a number of chemical mediators to be released from the mast cells and basophils. These include histamine, Eosinophil Chemotactic Factor (ECF-A) and leukotrienes. These chemical mediators are pharmacologically active at low concentrations and are partially responsible for the biological manifestations of the allergic response. (3)

The mechanism by which immunotherapy achieves hyposensitization is not completely understood. There is an increase in "blocking antibody" (lgG) titer and in some patients a decrease in specific IgE, a decrease in histamine release to specific allergen and an increase in suppressor celI population to specific allergen. These changes may occur only after prolonged therapy. (4)

TABLE A Potency of Commercially Available Allergy Laboratories, Inc. Non-standardized Grass Pollen Extracts (glycerinated 1:20 w/v) In-vitro data by ELISA Competition Assay

	Potency in BAU/ml		BAU/ml Range for Equivalence to Reference
GRASS POLLEN EXTRACT	Lot #1	Lot #2	
Bermuda	14,600	8,500	6,999- 14,310
Kentucky Blue	94,000	150,000	69,990-143,100
Meadow Fescue	275,000	105,000	69,990-143,100
Orchard	96,000	Not tested	69,990-143,100
Redtop	117,000	58,000	69,990-143,100
Perennial Rye	195,000	101,000	69,990-143,100
Sweel Vernal	67,000	72,000	69,990-143,100
Timothy	140,000	149,000	69,990-143,100

Clinical data from the Center for Biologics Evaluation and Research is shown in the following tables

TABLE B Puncture and Intradermal Data with CBER Grass Pollen References

1. Puncture Data with 10,000 BAU/ml Grass Pollen Extracts using bifurcated needle

Reference Pollen	FDA Lot #	N	P∑E (mm) Mean	P∑E (mm) Range	P∑W (mm) Mean	P∑W (mm) Range
Bermuda	E4-Ber	15	90.3	43-123	15.7	7-31
June	E3-Jkb	15	77.3	47-107	15.9	6-28
Meadow Fescue	E4-MF	15	81.1	57-115	11.9	7-22
Orchard	E4 Or	15	84.3	57-111	14.1	9-19
Perennial Rye	E10-Rye	15	92.3	73-135	17.5	6.36
Redtop	E4-Rt	15	77.1	42-98	14.1	8-19
Sweel Vernal	E4-SV	15	81.2	28-123	15.7	8-30
Timothy	E6-T	15	88.3	51-109	16.9	8-40

∑E = The sum of the longest diameter of erythema and the orthogonal erythema diameter measured at one half the longest erythema diameter.

∑W = The sum of the longest diameter of wheal and the orthogonal wheal diameter measured at one half the longest wheal diameter.

2. Intradermal Dose of CBER Grass Pollen References for 50mm Sum of Erythema (BAU_{50})

Reference Pollen	FDA Lot #	BAU_{50}/ml Mean	BAU_{50}/ml Range
Bermuda	E4-Ber	0.02	0.4 – 0.0003
June	E3-Jkb	0.02	0.1 – 0.004
Meadow Fescue	E4-MF	0.02	0.9 – 0.002
Orchard	E4 Or	0.02	1.9 – 0.002
Perennial Rye	E10-Rye	0.02	0.7 – 0.002
Redtop	E4-Rt	0.02	0.8 – 0.004
Sweel Vernal	E4-SV	0.02	1.0 – 0.002
Timothy	E6-Ti	0.02	0.6 – 0.002

INDICATIONS AND USAGE:

Standardized grass pollen extracts are used for the diagnosis and treatment of allergic disease to grass pollen. The standardized (Bioequivalent Allergy Unit) extract in these vials is designed primarily for the physician equipped to prepare dilutions and mixtures as required. **STANDARDIZED GRASS POLLEN EXTRACTS LABELED** IN BAU/ml **ARE NOT INTERCHANGEABLE WITH GRASS POLLEN EXTRACTS LABELED IN AU/ml OR WITH NON-STANDARDIZED (WEIGHT/VOLUME) GRASS POLLEN EXTRACTS.** Patients being switched from other types of extracts to Allergy Laboratories should have their dose adjusted. Diagnosis of allergic disease to these grasses is made through a combined medical history sufficiently complete to identify allergic symptoms to grass pollen and identification of grass allergy by diagnostic skin testing. It is recommended that diagnostic skin testing (scratch or puncture) be performed with 10,000 BAU/ml grass pollen extracts before testing with 100,000 BAU/ml grass pollen extracts. 10,000 BAU/mL and 100,000 BAU/ml grass pollen extracts for immunotherapy are available for previously treated patients to facilitate dose selection for safe switching from non-standardized to standardized extracts. Patients being treated with

grass pollen extracts for the first time can be initially immunized with dilutions prepared from the 10,000 BAU/ml extract (see Dosage and Administration). 100,000 BAU/ml grass pollen extract can be administered if the patient tolerates the 10,000 BAU/ml extract.

Grass pollen immunotherapy is intended for patients whose grass allergic symptoms cannot be satisfactorily controlled by avoidance of the offending allergen or by the use of symptomatic medications. (5)

CONTRAINDICATIONS:

There are no known absolute contraindications to hyposensitization therapy. See precautions section for pregnancy risks.

A patient without a history of grass pollen allergy symptoms and a positive skin test reaction to grass pollen should not be treated. The physician must determine if the benefits outweigh the risks in using these products for treating patients. The benefit to risk ratio should be carefully weighed especially where risks of immunotherapy are higher than usual. This includes severe unstable asthma, highly allergic patients who have had previous severe or unusual problems with injections, pregnancy, or any fragile general medical condition. This also includes patients where potential benefits are limited due to coexisting non-allergic disease such as: non-specific vasomotor rhinitis, nasal septal deviation, nasal polyps, COPD (chronic obstructive pulmonary disease), cardiovascular or other non-allergic respiratory disease.

WARNINGS

See WARNINGS box at the beginning of the instruction sheet.

Extracts standardized using the Bioequivalent Allergy Unit may be more or less potent than extracts based on AU/ml, weight to volume, or PNU methods of expressing potency. See Adverse Reactions section in this insert for a description of the possible local reactions and systemic reactions. Comparative skin tests can be performed to determine the relative potency before initial use of new extracts. DO NOT GIVE ALLERGY INJECTIONS INTRAVENOUSLY. Subcutaneous injections are recommended. Injections may produce large local reactions that may be painful to the patient. DO NOT GIVE FULL-STRENGTH INJECTIONS UNTIL COMPARATIVE SKIN TESTING IS PERFORMED. After inserting the needle, but before injecting extract, withdraw the plunger slightly. If blood appears in the syringe re-insert the needle at another site. Careful selection of dose and injection should prevent most systemic reactions.

PRECAUTIONS:

GENERAL:

The dosage should be reduced 50-75% from the previous dose when starting a patient on a new lot of standardized grass extract from the same manufacturer or from a different manufacturer. Table A in the Clinical Pharmacology section of this insert can be used for guidance when changing from a non-standardized grass extract to a standardized grass extract. The table shows the similarity in potency of two Iots of the non-standardized grass extracts with respect to the 10,000 BAU/ml standardized extracts. Comparative skin testing can be used to determine the dose.

A separate sterile tuberculin type syringe should be used with each patient to prevent cross contamination of extracts. This will also prevent transmission of disease such as hepatitis, AIDS and other infectious diseases. Aseptic technique should always be used when injections of allergenic extracts are administered.

INFORMATION FOR PATIENTS:

Because most serious reactions following the administration of allergenic extracts occur within 30 minutes of the injection, the patient should remain under observation for this period of time. The size of the local reaction should be recorded, because increasingly large local reaction may precede a subsequent systemic reaction with increasing dosage. The patient should be instructed to report any unusual reactions to the attention of the physician. In particular, this includes swelling and/or tenderness at the injection site or reactions such as rhinorrhea, sneezing, coughing, wheezing, shortness of breath, nausea, dizziness or faintness.

DRUG INTERACTIONS:

Patients who are taking non-selective beta blockers may be more reactive to skin tests and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. Antihistamines can significantly inhibit the immediate skin test reactions. If long acting antihistamines have been taken recently, it is recommended that they should be stopped for the following minimum intervals before skin testing is performed: at least 1 month for astemizole; 1 week for hydroxyzine or cetirizine; 4 to 7 days for Ioratadine; 3 to 4 days for terfenadine or fexofenadine; and 24 to 48 hours for other sustained release antihistamines. (6)

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

Long term studies with extracts have not been conducted in animals to determine their potential for carcinogenesis, mutagenesis, or impairment of fertility.

PREGNANCY:

Pregnancy Category C. Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Allergenic extracts should be given to a pregnant woman only if clearly needed.

Controlled studies of hyposensitization with moderate to high doses of allergenic extracts in pregnant women have failed to demonstrate any risk to the mother or fetus. (7)

Initiation of effective immunotherapy may be beneficial if it allows a pregnant patient to forego medications during the first trimester when the fetus is more vulnerable to teratogenic agents, or if it contributes to better control of asthma so the fetus has less likelihood of being damaged by hypoxemia.

However, with histamines known ability to contract uterine muscles any reaction which would release significant amounts of histamine such as hyposensitization overdose should be avoided. The physician must weigh the benefits of immunotherapy against the risk of anaphylactic reactions that could result in harm to the mother and/or fetus.

Hyposensitization should be used during pregnancy only if clearly necessary and administered cautiously. If a woman is on maintenance dose the occurrence of pregnancy is not an indication to stop injection therapy.

NURSING MOTHERS:

It is not known if allergenic extracts are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when extracts are administered to nursing women.

PEDIATRIC USE

Standardized grass pollen extract has not been studied in children, so the safety in children has not been established. The extracts may cause some pain or discomfort when injected, as well as systemic, adverse reactions (see Warnings and Adverse Reactions). The maximum tolerated dose may be less than the adult dose due to the smaller size of the child. Therefore, the volume of the dose may need to be adjusted from the adult schedules provided.

ADVERSE REACTIONS:

(1) Local Reactions:

Some swelling and redness at the site of injection is not unusual. Mild burning that occurs immediately after the injection is normal; this usually subsides in 10 to 20 seconds. If the swelling and redness persist for a period of 24 hours or longer this should be a sign to proceed with caution in increasing the dosage. With the next injection the dosage should remain the same or be decreased. Large local reactions may indicate that a systemic reaction could occur with the next injection if the dosage was increased. If a patient continues to have reactions at the maintenance dose, the patient is considered to have exceeded the maximum tolerated dosage.

(2) Systemic Reactions:

Systemic reactions occur infrequently but must be looked for in all patients, especially highly sensitive patients. Anaphylactic shock and death are always possible, therefore, physicians must be prepared for the treatment of these reactions. Systemic reactions can also be characterized by one or more of the following symptoms: angioedema, tachycardia, conjunctivitis, cough, fainting, hypotension, pallor, rhinitis, urticaria and wheezing.

Systemic reaction can be treated by the immediate application of a tourniquet above the site of injection and the administration of 0.3 to 0.5ml of 1:1000 Epinephrine-Hydrochloride subcutaneously or intramuscularly in the opposite arm. The dosage may be repeated two times at 15 minute intervals. Loosen the tourniquet at least every 10 minutes.

The pediatric dosage for 1:1000 Epinephrine-Hydrochloride is 0.05 to 0.1 ml for infants to 2 years of age; 0.15ml, for children 2 to 6 years; and 0.2ml, for children 6 to 12 years.

Patients should always be observed for at least 30 minutes after any injection. Hypotension can be reversed by using vasopressor agents and volume expanders. Parenteral aminophylline and inhalation bronchodilators may be required for bronchospasm. Oxygen may also be needed. Maintenance of an open airway is critical if upper airway obstruction is present. Adrenal corticosteroids and intravenous antihistamine can be given after adequate epinephrine and circulatory support has been administered. Physicians must be familiar with these systemic reactions and have all the equipment and drugs necessary for proper treatment. (8)

Serious adverse reactions can be reported to the US Food and Drug Administration MedWatch Program. The MedWatch forms can be obtained by calling 1-800-FDA-1088. The address is: MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787.

OVERDOSAGE:

Refer to Adverse Reactions section above.

DOSAGE AND ADMINISTRATION:

DIAGNOSTIC SKIN TESTING: These products are used to determine a patient's sensitivity to specific antigens and aid in the diagnosis and treatment of atopic diseases. After a thorough history, a decision can be made as to which allergens will be appropriate to use for testing. The recommended procedure is to initially perform puncture tests, then follow with intradermal tests. For enhanced safety, scratch or puncture test with 10,000 BAU/ml before testing with 100,000 BAU/ml. See recommended dosage below:

SCRATCH OR PUNCTURE TEST:	Concentration BAU/ml	Dosage
	Bermuda Grass 10,000	1 drop

	Other Grasses	
	10,000	1 drop
	100,000	1 drop
INTRADERMAL TEST:	Concentration BAU/ml	Dosage ml
When scratch or puncture test is negative:	100	0.02
When scratch or puncture test is positive:	*	0.02

* See Table B for information regarding range of BAU/ml that elicits a 50mm response for highly reactive patients. The negative intradermal control used for the 100 BAU/ml concentration should contain 0.5% (v/v) glycerin.

FREQUENCY OF ADMINISTRATION:

The number of skin tests applied at one time will depend on the particular patient and their allergic history. These tests should be performed and observed in 15 to 20 minutes. Additional tests may be applied in sequence. Perform tests on the anterolateral aspect of the upper arm on an area that permits the effective application of a tourniquet proximal to the site of the test. The skin at the site of injection should be disinfected with rubbing alcohol before testing.

Puncture testing: Apply one drop of extract to the skin. Pierce the drop of extract and skin using a sterile hypodermic needle or vaccinating needle. Maintain the needle perpendicular to the skin surface and rock the needle back and forth to produce a small hole without bleeding. Do not rotate or gouge the needle. Remove needle from skin and wipe excess extract from skin surface.

Scratch testing: Using a scarifier or needle, make a scratch 1/16 inch long on the epidermis penetrating the outer cornified area but being careful not to draw blood. Apply one drop of extract to the scratch.

Intradermal testing: Use a separate sterile syringe (tuberculin type equipped with a 27 gauge by 3/8 inch needle with intradermal bevel) for each antigen. The tests are made by injecting 0.02ml of allergen into the epidermis. If the test has been performed properly, the solution should raise a bleb 2 to 3mm in diameter. If the bleb does not appear, the injection was made too deeply.

A negative control consisting of the same solution that the extract was prepared in, should be applied to one of the sites in the same manner as the tests being performed. For example, the negative intradermal control should contain 0.5% (v/v) glycerin, if a 100 BAU/ml concentration grass is used for intradermal testing. Histamine phosphate should be used as a positive control for evaluation of skin testing. Histamine phosphate is available from other manufacturers. See their directions for use, for recommended dosage and interpretation of results.

A positive reaction usually develops in 15 to 20 minutes. The positive response is a wheal and flare reaction that is larger than the negative control and judged on the size of the reaction. Scratch or puncture tests may not elicit as large and well defined reaction as the intradermal. (5)

The following grading system for intradermal testing is recommended (9):

Reaction	Erythema	Wheal
0	<5mm	<5mm
+/-	5-10mm	5-10mm
1+	11-20mm	5-10mm
2+	21-30mm	5-10mm
3+	31-40mm	10-15mm or with pseudopods
4+	>40mm	>15mm or with many pseudopods

IMMUNOTHERAPY:

The following are two methods of injection therapy:

1. Pre-seasonal in which treatment is begun three months before seasonal difficulty begins and brought to maintenance dose by injections 4 to 7 days apart and discontinued after that season ends.

2. Perennial treatment is the recommended mode of therapy in which the patient is, by injection therapy, brought up to tolerated maintenance dose and remains at that dose until amelioration of allergic symptoms occurs. Injections may be given at intervals of 4 to 7 days.

Allergenic extracts must be diluted before use. Normally immunotherapy can be started with a 1 BAU/ml dilution. If a patient appears to be extremely sensitive, based on skin testing results, dilutions of the extract can further be made before injections are started. See Table B for additional information. The following are suggested procedures for making a proper dilution series. Recommended diluents contain 0.9% sodium chloride and 0.4% phenol as a preservative. Dlluents with HSA (Human Serum Albumin) as a stabilizer can also be used. Allergenic extracts should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

TEN FOLD DILUTION SERIES:

EXTRACT VOLUME	EXTRACT CONCENTRATION BAU/ml	DILUENT VOLUME	DILUTION CONCENTRATION BAU/ml
1 part	100,000 +	9 parts =	10,000
1 part	10,000 +	9 parts =	1,000
1 part	1,000 +	9 parts =	100
1 part	100 +	9 parts =	10
1 part	10 +	9 parts =	1

Perennial treatment may be started using the following dosage and dilution schedule. (Modified from Reference 10) **This schedule is only illustrative and may not be applicable to** all patients, **since the degree of sensitivity to grass allergens differs among individuals. The dose administered must be adjusted based on the patient's sensitivity and tolerance.** Initial dose can be based on end point titration using a dose that elicits a 1-2+ reaction. Maintenance dose is based on patient tolerance.

Dose #	Dose Volume (ml)	Concentration
1	0.05	1 BAU/ml
2	0.10	
3	0.20	
4	0.30	
5	0.40	
6	0.50	
7	0.05	10 BAU/ml
8	0.10	
9	0.20	
10	0.30	
11	0.40	
12	0.50	
13	0.05	100 BAU/ml
14	0.10	
15	0.20	
16	0.30	

17	0.40	
18	0.50	
19	0.05	1,000 BAU/ml
20	0.10	
21	0.20	
22	0.30	
23	0.40	
24	0.50	
25	0.05	10,000 BAU/ml
26	0.10	
27	0.20	
28	0.30	
29	0.40	
30	0.50	
31	0.05	100,000 BAU/ml
32	0.10	
33	0.20	
34	0.30	
35	0.40	

Gradually increase the dose as outlined in the schedule. If you give a dose that causes a mild local reaction (manifested by warmth or redness) repeat the same dose. If the reaction is severe or systemic (manifested as hives, asthma, or hay fever) drop back a dose in schedule and build again. If a severe local reaction or a systemic reaction is again encountered, this should be considered more than the maximum tolerance for this patient. The maintenance dose is the largest dose that relieves symptoms without producing local reactions. The size and interval of doses will vary and can be adjusted as necessary. The normal interval between doses is 4 to 7 days. The usual duration of treatment has not been established. A period of two or three years of injection therapy constitutes an average minimum course of treatment.

HOW SUPPLIED:

Bulk extract (stock concentrate) in 50% (v/v) glycerin containing 10,000 BAU/ml or 100,000 BAU/ml is supplied in 10ml, 30ml, and 50ml vials. Bermuda Grass bulk extract is available in 10,000 BAU/ml only. Scratch testing for Bermuda Grass in 50% (v/v) glycerin containing 10,000 BAU/ml is supplied in 2ml dropper vials. Scratch testing for the other grasses in 50% (v/v) glycerin containing 10,000 BAU/ml or 100,000 BAU/ml is supplied in 2ml dropper vials. Intradermal testing (aqueous) for all standardized grasses containing 100 BAU/ml is supplied in 5ml vials.

STORAGE:

These extracts should be stored at 2 to 8 degrees Celsius. Excessive heating (above room temperature) and repeated freeze-thawing should be avoided. The dating period (expiration date) is shown on the vial label. Once extracts are diluted the shelf life decreases. Extracts should be reordered when out of date. Please allow a minimum of three (3) weeks for delivery due to the holding period for sterility testing.

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ALLERGY LABORATORIES, INC.
U.S. License #103
Oklahoma City, OK 73109 • (405) 235-1451 • (800) 654-3971

PRINCIPAL DISPLAY PANEL

ALLERGENIC EXTRACT

STANDARDIZED POLLEN

Preservative 50% Glycerin (v/v)

Dose/Route: See Enclosure

Store at 2-8°C, NON RETURNABLE

ALLERGY

LABORATORIES, INC

Oklahoma City, OK 73109

U.S Govt. License No. 103

STANDARDIZED BERMUDA GRASS POLLEN

cynodon dactylon pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-084
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54575-084-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-084-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-084-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-084-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA101379	05/29/1997	

STANDARDIZED KENTUCKY BLUEGRASS POLLEN

poa pratensis pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-087
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54575-087-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-087-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-087-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-087-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101380	05/29/1997	

STANDARDIZED MEADOW FESCUE GRASS POLLEN

festuca elatior pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-092
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FESTUCA PRATENSIS POLLEN (UNII: A0WFQ8P6N1) (FESTUCA PRATENSIS POLLEN - UNII:A0WFQ8P6N1)	FESTUCA PRATENSIS POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54575-092-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-092-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-092-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-092-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101381	05/29/1997	

STANDARDIZED ORCHARD GRASS POLLEN

dactylis glomerata pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-097
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:54575-097-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-097-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-097-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-097-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101382	05/29/1997	

STANDARDIZED REDTOP GRASS POLLEN

agrostis alba pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-099
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54575-099-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-099-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-099-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-099-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101383	05/29/1997	

STANDARDIZED PERENNIAL RYEGRASS GRASS POLLEN

lolium perenne pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-102
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54575-102-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-102-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-102-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-102-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101384	06/25/1997	

STANDARDIZED SWEET VERNAL GRASS POLLEN

anthoxanthum odoratum pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-106
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54575-106-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-106-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-106-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-106-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101385	05/29/1997	

STANDARDIZED TIMOTHY GRASS POLLEN

phleum pratense pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54575-107
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	50 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.166 g in 100 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.091 g in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54575-107-02	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:54575-107-10	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:54575-107-30	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:54575-107-50	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101386	05/29/1997	

Labeler - Allergy Laboratories, Inc. (007191810)

Establishment

Name	Address	ID/FEI	Business Operations
Allergy Laboratories, Inc.		007191810	MANUFACTURE

Revised: 3/2010 Allergy Laboratories, Inc.