STANDARDIZED BERMUDA GRASS POLLEN - standardized bermuda grass pollen injection, solution
STANDARDIZED MEADOW FESCUE GRASS POLLEN - standardized meadow fescue grass pollen injection, solution
STANDARDIZED ORCHARD GRASS POLLEN - standardized orchard grass pollen injection, solution
STANDARDIZED REDTOP GRASS POLLEN - standardized redtop grass pollen injection, solution
STANDARDIZED PERENNIAL RYE GRASS POLLEN - standardized perennial rye grass pollen injection, solution
STANDARDIZED TIMOTHY GRASS POLLEN - standardized timothy grass pollen injection, solution
STANDARDIZED KENTUCKY (JUNE) BLUEGRASS - standardized kentucky (june) bluegrass injection, solution
STANDARDIZED SWEET VERNAL GRASS POLLEN - standardized sweet vernal grass pollen injection, solution
MIXTURE OF FOUR STANDARDIZED GRASSES - mixture of four standardized grasses injection, solution
MIXTURE OF FIVE STANDARDIZED GRASSES - mixture of five standardized grasses injection, solution
MIXTURE OF SIX STANDARDIZED GRASSES - mixture of six standardized grasses injection, solution
MIXTURE OF SEVEN STANDARDIZED GRASSES - mixture of seven standardized grasses injection, solution
MIXTURE OF EIGHT STANDARDIZED GRASSES - mixture of eight standardized grasses injection, solution
MIXTURE OF TWENTY-TWO STANDARDIZED AND NON-STANDARDIZED GRASSES - mixture of twenty-two standardized and non-standardized grasses injection, solution
MIXTURE OF STANDARDIZED AND NON-STANDARDIZED SOUTHERN GRASSES - mixture of standardized and non-standardized southern grasses injection, solution
MIXTURE OF STANDARDIZED AND NON-STANDARDIZED INLAND GRASSES - mixture of standardized and non-standardized inland grasses injection, solution
MIXTURE OF STANDARDIZED AND NON-STANDARDIZED SOUTHEASTERN GRASSES - mixture of standardized and non-standardized southeastern grasses injection, solution
MIXTURE OF STANDARDIZED AND NON-STANDARDIZED COASTAL GRASSES - mixture of standardized and non-standardized coastal grasses injection, solution
Antigen Laboratories, Inc.

ALLERGENIC EXTRACT

WARNINGS

Standardized Grass Pollen extracts labeled in Bioequivalent Allergy Units (BAU/ml) are not interchangeable with grass extracts labeled in Allergy Units (AU/ml) or with non-standardized grass pollen extracts. Standardized Grass Pollen allergenic extract is intended for use by physicians or under the guidance of physicians who are experienced in the administration of allergenic extracts for diagnosis and/or immunotherapy and in emergency care of anaphylaxis. Standardized Grass Pollen extracts are not interchangeable with other allergenic extracts. Patients being switched from other manufacturers' extracts to Antigen Laboratories' allergenic extracts should have their dose adjusted. (See "WARNINGS" and "DOSAGE AND ADMINISTRATION" sections.)

Caution is imperative when switching from non-standardized grass pollen to Standardized Grass Pollen extracts. Standardized Grass Pollens may have equal, greater, or lesser potency than non-standardized grass pollen. Refer to "CLINICAL PHARMACOLOGY" Table 2 and "DOSAGE AND ADMINISTRATION" sections.

Severe systemic reactions may occur with all allergenic extracts. In certain individuals, these Iife-threatening reactions may result in death. Patients should be observed for at least 20 minutes following allergenic extract injections. Treatment and emergency measures, as well as personnel trained in their use, must be available in the event of a life-threatening reaction. Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and/or death. Report serious adverse events to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, phone 1-800-FDA-1088.

Extreme caution must be exercised in treating patients with steroid dependent or labile asthma, chronic obstructive pulmonary disease, and cardiovascular disease.

Patients being switched from one lot of extract to another lot from the same manufacturer, should have dose reduced by 75%.

Allergenic extracts should not be injected intravenously. Deep subcutaneous routes have proven to be safe. See the "WARNINGS", "PRECAUTIONS", "ADVERSE REACTIONS" and "OVERDOSAGE" sections.

Patients receiving beta-blockers may not be responsive to epinephrine or inhaled bronchodilators. Patients with respiratory obstruction not responding to parenteral or inhaled bronchodilators may require theophylline, oxygen, intubation and Iife support systems. Parenteral fluid and/or plasma expanders may be utilized for treatment of shock. Adrenocorticosteroids may be administered parenterally or intravenously. Refer to "ADVERSE REACTIONS" section.

DESCRIPTION

Antigen Laboratories' Standardized Grass Pollen allergenic extracts are sterile and intended for dilution prior to skin testing and/or immunotherapy. The route of administration for immunotherapy is subcutaneous. The routes of administration for diagnostic purposes are intradermal or prick-puncture of the skin. Standardized Grass Pollen allergenic extract labeled in BAU/ml is not interchangeable with grass pollen extract labeled in AU/ml or with non-standardized grass pollen extract.

Potency of Standardized Grass Pollen allergenic extract is determined by comparison to a Center for Biologics Evaluation and Research (CBER) approved reference. References are available for pollen extracts of Orchard Grass (*Dactylis glomerata*), Perennial Rye Grass (*Lolium perenne*), Timothy Grass (*Phleum pratense*), Redtop Grass (*Agrostis alba*), Kentucky (June) Bluegrass (*Poa pratensis*), Bermuda Grass (*Cynodon dactylon*), Meadow Fescue Grass (*Festuca elatior*), and Sweet Vernal Grass (*Anthoxanthum odoratum*). Quantitative skin testing is used by CBER to establish reference's potency as Bioequivalent Allergy Units (BAU). CBER reference labeled 10,000 BAU/ml produces a sum of erythema diameter of 50 mm with highly puncture reactive subjects at an intradermal dilution of approximately 1:500,000.[11,17] CBER references labeled 100,000 BAU/ml produce a SumE=50 mm at an intradermal dilution of 1:5,000,000. Relative potency of Standardized Grass Pollen allergenic

extracts to CBER reference is determined by Enzyme-linked Immunosorbent Assay (ELISA).

In addition to relative potency testing of Standardized Grass Pollen extract the following testing is performed:

1. Microscopic examination to confirm identity and purity of source pollens.
2. lsoelectric focusing (IEF) pattern of source material is compared to respective CBER reference extract.
3. lsoelectric focusing pattern of final 100,000 BAU/ml (10,000 BAU/ml Bermuda Grass) product is compared to CBER reference extract.
4. Ninhydrin Protein Analysis.
5. Glycerine Analysis. (A minimum of 50% v/v glycerine for optimal stability during the entire dating period.)
6. Sterility Testing.
7. Animal Safety Testing.

Standardized Grass Pollen allergenic extracts are extracted at 1:10 weight to volume (w/v) ratio of source material to extraction fluid. Bermuda Grass is only available in 10,000 BAU/ml. Standardized Grass Pollen extracts are diluted after extraction to fall in acceptable relative potency range for a 100,000 BAU/ml or 10,000 BAU/ml (Bermuda Grass) product. Standardized Grass Pollen allergenic extracts (except Bermuda) of 10,000 BAU/ml potency are prepared by diluting the 100,000 BAU/ml extract 1:10 with extracting fluid.

Various mixtures of eight Standardized Grass Pollen extracts are available. Mixtures of Standardized Grass Pollen extracts with non-standardized grass pollen extracts are available. Concentrations of Standardized Grass Pollen extracts (BAU/ml) and non-standardized grass pollen extracts (w/v) in a mixture are printed on the last page of this circular, if applicable.

Active Ingredients: Allergens are described by common and scientific name on container label or last page of this circular. Preservative is 50% v/v glycerine. Inactive ingredients are 0.95% sodium chloride, 0.24% sodium bicarbonate and water for injection.

CLINICAL PHARMACOLOGY

Studies indicate allergic individuals produce immunoglobulins of the IgE class in response to exposure to grass pollens. Subsequent exposure to grass pollen results in a combination of allergen with IgE antibody fixed on mast cells or basophil membranes. This cross-linking results in stimulation of mast cell which leads to release and generation of pharmacologically active substances that produce immediate hypersensitivity reaction.[15]

The mode of action of immunotherapy with allergenic extracts is still being investigated. Subcutaneous injections of increasing doses of allergenic extract into patients with allergic disease have been shown to result in both humoral and cellular changes. These include production of allergen specific IgG antibodies, suppression of histamine release from target cells, decrease in circulating levels of antigen specific IgE antibody over long periods of time and suppression of peripheral blood T-Iymphocyte cell responses to antigen. [5,9,10]

Puncture and intradermal data from skin testing with CBER grass reference is summarized in Table 1. Fifteen patients with clinical symptoms when exposed to grass pollen were included in the study. The mean sum erythema (PSumE) and mean sum wheal (PSumW) from puncture testing is listed in Table 1A. The Intradermal Dilution for 50 mm Sum of Erythema determines Bioequivalent ALlergy Units ($ID_{50}EAL$) method was used by CBER personnel to calculate intradermal dose (BAU/ml). The calculated mean and ranges of intradermal dose (BAU/ml) for 50 mm sum of erythema using reference extract is summarized in Table 1B. [17]

TABLE 1

Puncture and Intradermal Data with CBER Grass Reference

A. Puncture Data with 10,000 BAU/ml Grass Extracts (Bifurcated needle)

Reference	FDA Lot	$_{N}$	PSumE (mm)	PSumE (mm)	PSumW (mm)	PSumW (mm)

Pollen	#	N	Mean	Range	Mean	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
Sweet Vernal	E4-Sv	15	81.2	28-123	15.7	8-30
Timothy	E6-Ti	15	88.3	51-109	16.9	8-40

B. Calculated Intradermal Dose (BAU50) of CBER Grass Reference for 50mm Sum of Erythema.

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
Sweet Vernal	E4-Sv	0.02	1.0-0.002
Timothy	E6-Ti	0.02	0.6-0.002

Relative potency value of various lots of non-standardized grass pollen extracts are summarized in Table 2. The acceptable BAU/ml ranges for equivalency to FDA reference for a 100,000 BAU/ml product are 69,900-143,100 at n=3, 73,300-136,400 at n=4 and 75,800-132,000 at n=5. Acceptable equivalency ranges for a 10,000 BAU/ml product are 6,990-14,310 at n=3, 7,330-13,640 at n=4 and 7,580-13,200 at n=5 (n=number of tests performed).

TABLE 2
BAU/ml Estimate of Non-standardized Grass Pollen Allergenic Extracts
Commercially Distributed by Antigen Laboratories, Inc.

50% v/v Glycerinated Extract	w/v	Lot #	N	BAU/ml Range
Redtop	1:20	R19101193	3	92,350-109,340
Redtop	1:33	R19022194	3	30,410-51,830
Meadow Fescue	1:20	F09062493	3	196,270-308,200
Meadow Fescue	1:33	F09092993	3	141,670-295,730
Bermuda	1:20	B29121393	3	11,263-13,359
Bermuda	1:33	B29013194	3	6,299-10,195
Kentucky Bluegrass	1:20	J05012494	3	73,580-116,880
Kentucky Bluegrass	1:33	J05120793	4	32,220-57,940
Sweet Vernal	1:20	S37031594	3	107,300-191,360
Sweet Vernal	1:20	S37042495	3	93,180-107,120
Perennial Rye	1:20	R21032194	3	82,600-136,070
Perennial Rye	1:33	R21011393	3	65,770-127,700

Timothy	1:20	T18013194	3	81,320-99,470
Timothy	1:20	T18121994	3	45,340-68,990
Orchard	1:20	O12032593	5	83,690-110,590
Orchard	1:33	O12011994	4	56,550-77,150

INDICATIONS AND USAGE

Allergenic extract is indicated for diagnostic testing and treatment (immunotherapy) of patients whose histories indicate allergic symptoms upon natural exposure to grass allergens. Confirmation is determined by skin testing. 10,000 BAU/ml extracts are intended for percutaneous testing. If negative, 100,000 BAU/ml products can be used for percutaneous test. Dilutions made from 10,000 BAU/ml products are indicated for immunotherapy of previously untreated patients. If 10,000 BAU/ml product is tolerated and symptoms persist, dilutions made from 100,000 BAU/ml can be administered.
Standardized Grass Pollen extracts labeled in Bioequivalent Allergy Units (BAU/ml) are not interchangeable with grass pollen extracts labeled In Allergy Units (AU/ml) or with non-standardized grass pollen extracts.

CONTRAINDICATIONS

Do not administer in the presence of diseases characterized by bleeding diathesis. Individuals with autoimmune disease may be at risk of exacerbating symptoms of underlying disease, possibly due to routine immunization. Recent myocardial infarction patients may not tolerate immunotherapy. Children with nephrotic syndrome probably should not receive injections due to a possibility of immunization causing exacerbation of their nephrotic disease.

Standardized Grass Pollen extract is not intended for the treatment of patients who do not experience allergic symptoms upon natural exposure to the allergen.

Allergenic extracts are not intended for diagnosing patients who do not manifest immediate hypersensitivity reactions to the allergenic extract when skin tested.

WARNINGS

Refer to boxed "WARNINGS", "PRECAUTIONS", "ADVERSE REACTIONS" and "OVERDOSAGE" sections for additional information on serious adverse reactions and steps to be taken, if any occur.

Extreme caution is necessary when using diagnostic skin tests or injection treatment in highly sensitive patients who have experienced severe symptoms or anaphylaxis by natural exposure, or during previous skin testing or treatment. *IN THESE CASES THE POTENCY FOR SKIN TESTS AND THE ESCALATION OF THE TREATMENT DOSE MUST BE ADJUSTED TO THE PATIENTS SENSITIVITY AND TOLERANCE.*

Benefit versus risk needs to be evaluated in steroid dependent asthmatics, patients with unstable asthma or patients with underlying cardiovascular disease.

Injections should never be given intravenously. A 5/8 inch, 25 gauge needle on a sterile syringe allows deep subcutaneous injection. Withdraw plunger slightly after inserting needle to determine if a blood vessel has been entered.

Proper measurement of dose and caution in making injection will minimize reactions.
Adverse reactions to allergenic extracts are usually apparent within 20-30 minutes following injection of immunotherapy.

Extract should be temporarily withheld or dosage reduced in case of any of the following conditions: 1) flu or other infection with fever; 2) exposure to excessive amounts of allergen prior to injection; 3) rhinitis and/or asthma exhibiting severe symptoms; 4) adverse reaction to previous injection until cause of reaction has been evaluated by physician supervising patient's immunotherapy program.

PRECAUTIONS

General:

Immunotherapy must be given under physician's supervision. Sterile solutions, vials, syringes, etc. must be used. Aseptic technique must be observed in making dilutions from stock concentrates. The usual precautions in administering allergenic extracts are necessary, refer to boxed WARNINGS and "WARNINGS" section. Sterile syringe and needle must be used for each individual patient to prevent transmission of serum hepatitis, Human Immunodeficiency Virus (HIV) and other infectious agents.

Epinephrine 1:1000 should be available. Refer to "OVERDOSAGE" section for description of treatment for anaphylactic reactions.

Information for Patients:

Patient should remain under observation of a nurse, physician, or personnel trained in emergency measures for at least 20 minutes following immunotherapy injection. Patient must be instructed to report any adverse reactions that occur within 24 hours after injection. Possible adverse reactions include unusual swelling and/or tenderness at injection site, rhinorrhea, sneezing, coughing, wheezing, shortness of breath, nausea, dizziness, or faintness. Immediate medical attention must be sought for reactions that occur during or after leaving physician's office.

Pregnancy Category C:

Animal reproduction studies have not been conducted with allergenic extracts. It is not known whether allergenic extracts cause fetal harm during pregnancy or affect reproductive capacity. A systemic reaction to allergenic extracts could cause uterine contractions leading to spontaneous abortion or premature labor. Allergenic extracts should be used during pregnancy only if potential benefit justifies potential risk to fetus.[6]

Nursing Mothers:

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

Pediatric Use:

Allergenic extracts have been used routinely in children and no special problems of safety or specific hazard have been found. Children can receive the same dose as adults. Discomfort is minimized by dividing the dose in half and administering injection at two different sites. [13,14]

Carcinogenicity, Mutagenicity, Impairment of Fertility:

Long term animal studies have not been conducted with Standardized Grass Pollen allergenic extracts to evaluate carcinogenicity, mutagenicity or fertility impairment.

Drug Interactions:

Antihistamines. Antihistamines inhibit the wheal and flare reaction. The inhibitory effect of conventional antihistamines varies from 1 day up to 10 days, according to the drug and patient's sensitivity. Long acting antihistamines (e.g., astemizole) may inhibit the wheal and flare for up to forty days.

Imipramines. phenothiazines, and tranquilizers. Tricyclic antidepressants exert a potent and sustained decrease of skin reactions to histamine. This effect may last for a few weeks. Tranquilizers and antiemetic agents of the phenothiazine class have H, antihistaminic activity and can block skin tests.[1]

Corticosteroids. Short-term (less than 1 week) administration of corticosteroids at the therapeutic doses used in asthmatic patients does not modify the cutaneous reactivity to histamine, compound 48/80, or allergen. Long-term corticosteroid therapy modifies the skin texture and makes the interpretation of immediate skin tests more difficult.[1]

Theophylline. It appears that theophylline need not be stopped prior to skin testing.[1]

Beta-blockers.*PATIENTS RECEIVING BETA-BLOCKERS MAY NOT BE RESPONSIVE TO*

EPINEPHRINE OR INHALED BRONCHODILATORS. The following are commonly prescribed *BETA-BLOCKERS*: Levatol, Lopressor, Propanolol Intersol, Propanolol HCL, Blocadren, Propanolol, Inderal-LA, Visken, Corgard, Ipran, Tenormin, Timoptic. Ophthalmic beta-blockers: Betaxolol, Levobunolol, Timolol, Timoptic. Chemicals that are beta-blockers and may be components of other drugs: Acebutolol, Atenolol, Esmolol, Metoprolol, Nadolol, Penbutolol, Pindolol, Propanolol, Timolol, Labetalol, Carteolol.

Beta-adrenergic agents. Inhaled $beta_2$ agonists in the usual doses used for the treatment of asthma do not usually inhibit allergen-induced skin tests. However, oral terbutaline and parenteral ephedrine were shown to decrease the allergen-induced wheal.

Cromolyn. Cromolyn inhaled or injected prior to skin tests with allergens or degranulating agents does not alter the skin whealing response.[1]

Other drugs. Other drugs have been shown to decrease skin test reactivity. Among them, dopamine is the best-documented compound.[1]

Specific immunotherapy. A decreased skin test reactivity has been noticed by many authors for patients undergoing specific immunotherapy with pollen extracts, grass pollen allergoids, mite, or hymenoptera venoms, or in professional beekeepers who are spontaneously desensitized. Finally, it was shown that specific immunotherapy in patients treated with ragweed pollen extract induced a decreased late-phase reaction.[1]

ADVERSE REACTIONS

Adverse reactions include, but are not limited to urticaria; itching; edema of extremities; respiratory wheezing or asthma; dyspnea; cyanosis; tachycardia; lacrimation; marked perspiration; flushing of face, neck or upper chest; mild persistent clearing of throat; hacking cough or persistent sneezing.

1) Local Reactions

A mild burning immediately after injection is expected; this usually subsides in 10-20 seconds. Prolonged pain or pain radiating up arm is usually the result of intramuscular injection, making this injection route undesirable. Subcutaneous injection is the recommended route.

Small amounts of erythema and swelling at the site of injection are common.
Reactions should not be considered significant unless they persist for at least 24 hours or exceed 50 mm in diameter.

Larger local reactions are not only uncomfortable, but indicate the possibility of a severe systemic reaction if dosage is increased. In such cases dosage should be reduced to the last level not causing reaction and maintained for two or three treatments before cautiously increasing.

Large, persistent local reactions or minor exacerbations of the patient's allergic symptoms may be treated by local cold applications and/or use of oral antihistamines.

2) Systemic Reactions

Systemic reactions range from mild exaggeration of patient's allergic symptoms to anaphylactic reactions.[12] Very sensitive patients may show a rapid response. It cannot be overemphasized that, under certain unpredictable combinations of circumstances, anaphylactic shock is always a possibility. Fatalities are rare but can occur.[16] Other possible systemic reaction symptoms are fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis, and urticaria.[8,9]

Careful attention to dosage and administration limit such reactions. Allergenic extracts are highly potent to sensitive individuals and OVERDOSE could result in anaphylactic symptoms. Therefore, it is imperative that physicians administering allergenic extracts understand and prepare for treatment of severe reactions. Refer to "OVERDOSAGE" section.

OVERDOSAGE

Refer to "WARNINGS", "PRECAUTIONS", and "ADVERSE REACTIONS" sections for signs and symptoms of overdose.

If a systemic or anaphylactic reaction does occur, apply tourniquet above the site of allergenic

extract injection and inject intramuscularly or subcutaneously 0.3 to 0.5 ml of 1:1000 Epinephrine-hydrochloride into the opposite arm or gluteal area. Repeat dose in 5-10 minutes if necessary. Loosen tourniquet briefly at 5 minute intervals to prevent circulatory impairment. Discontinue use of the tourniquet after hour.

The epinephrine HCL 1:1000 dose for infants to 2 years is 0.05 to 0.1 ml; for children 2 to 6 years it is 0.15 ml; for children 6 to 12 years it is 0.2 ml. Symptoms of progressive anaphylaxis include airway obstruction and/or vascular collapse. After administration of epinephrine, profound shock and vasomotor collapse should be treated with intravenous fluids and possibly vasoactive drugs. Monitor airways for obstruction. Oxygen should be given by mask if indicated.

Antihistamines, H_2 antagonist, bronchodilators, steroids and theophylline may be used as indicated after giving adequate epinephrine and circulatory support.[12]

Patients who have been taking a beta-blocker may be unresponsive to epinephrine or beta-adrenergic drugs (Alupent). These drugs should be administered even though a beta-blocker may have been taken. The following treatment will be effective whether or not patient is taking a beta-blocker: Aminophylline IV, slow push or drip, Atrovent (Ipratropium bromide) Inhaler, 3 inhalations repeated, Atropine, 0.4 mg/ml, 0.75 to 1.5 ml lM or IV, Solu-Cortef, 100-200 mg IM or IV, Solu-Medrol, 125 mg IM or IV, Glucagon, 0.5-1 mg IM or IV, Benadryl, 50 mg IM or IV, Cimetidine, 300 mg IM or IV, Oxygen via ambu bag.

DOSAGE AND ADMINISTRATION

Refer to "STORAGE" section for proper storage condition for allergenic extract.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Some allergenic extracts naturally precipitate.

Precaution is necessary when using grass pollen extract mixtures. Potency may be additive and may equal the total potency of the grass pollen extracts in the mixture. Careful attention to container label and/or package insert in regard to BAU/ml of grass pollen extracts from which mixture is derived is important.

Physicians undertaking immunotherapy should be concerned with patient's degree of sensitivity. The initial dilution of allergenic extract, starting dose and progression of dosage must be carefully determined on the basis of the patient's history and results of skin tests. (SEE "INDICATIONS AND USAGE" section.) Strongly positive skin tests may be risk factors for systemic reactions. Less aggressive immunotherapy schedules may be indicated for such patients.

PRICK-PUNCTURE TESTING: To identify grass sensitive individuals and as a safety precaution, it is recommended that a prick or puncture test be performed prior to initiating very dilute intradermal testing. Prick (puncture) testing is performed by placing a drop of extract on skin and puncturing skin through the drop with a prick-puncture device. The most satisfactory sites on the back for skin testing are from posterior axillary fold to 2.5 cm from the spinal column, and from the top of the scapula to the lower rib margins. The best areas on the arms are the volar surfaces from the axilla to 2.5 or 5 cm above the wrist, skipping the anticubital space. It is recommended that 10,000 BAU/ml Standardized Grass Pollen extract be used for initial puncture testing because 100,000 BAU/ml extracts produce very large puncture reactions in highly reactive individuals.[18] A positive reaction is approximately 10-15 mm erythema with 2.5 mm wheal.

Smaller, less conclusive reactions may be considered positive in conjunction with a definitive history of symptoms on exposure to allergen. Less sensitive individuals can be tested intradermally with appropriately diluted extract. (See Intradermal Testing.)

A positive control using histamine phosphate identifies patients whose skin may not react due to medications, metabolic or other reasons. A negative control (50% glycerine for prick-puncture testing) would exclude false-positive reactions due to ingredients in diluent or patients who have dermatographism.

SERIAL DILUTIONS
APPROXIMATE BAU/ml RESULTING FROM 1:10 DILUTION

OF ALLERGENIC EXTRACT CONCENTRATE

DILUTION #	DILUTION EXPONENT	100,000 BAU/ML	10,000 BAU/ML
1	10^{-1}	10,000	1,000
2	10^{-2}	1,000	100
3	10^{-3}	100	10
4	10^{-4}	10	1
5	10^{-5}	1	0.1
6	10^{-6}	0.1	0.01
7	10^{-7}	0.01	0.001
8	10^{-8}	0.001	0.0001
9	10^{-9}	0.0001	0.00001
10	10^{-10}	0.00001	0.000001

SERIAL DILUTIONS
APPROXIMATE BAU/ml RESULTING FROM 1:5 DILUTION
OF ALLERGENIC EXTRACT CONCENTRATE

DILUTION #	DILUTION EXPONENT	100,000 BAU/ML	10,000 BAU/ML
1	5^{-1}	20,000	2,000
2	5^{-2}	4,000	400
3	5^{-3}	800	80
4	5^{-4}	160	16
5	5^{-5}	32	3.2
6	5^{-6}	6.4	0.64
7	5^{-7}	1.28	0.128
8	5^{-8}	0.256	0.0256
9	5^{-9}	0.0512	0.00512
10	5^{-10}	0.01024	0.001024
11	5^{-11}	0.002048	0.0002048

INTRADERMAL TESTING: Upper to lower arm are the usual locations for skin testing. A sterile, disposable syringe and needle is used for each extract tested. Intracutaneous test dilutions should be made with aqueous diluent. Three-fold, five-fold or ten-fold dilutions may be prepared from stock concentrates. (1) Start testing with the most dilute allergenic extract concentration. (2) A volume of 0.01-0.02 ml should be injected slowly into the superficial skin layers making a small bleb (superficial wheal). (3) For patients with grass sensitivity based on puncture reactivity, a concentration of approximately 0.02 BAU/ml (10,000 BAU/ml 5^{-8} or 10^{-6} or 100,000 BAU/ml 5^{-10} or 10^{-7} dilution) should be used for initial skin testing ("CLINICAL PHARMACOLOGY", Table 1B). Reactions to skin testing are graded 0 to 4+ according to size of wheal and erythema produced (refer to chart below). The reactions should be read after fifteen minutes.

EVALUATION OF SKIN REACTIONS

GRADE	mm ERYTHEMA	mm WHEAL
0	less than 5	less than 5

+/-	5-10	5-10
1+	11-20	5-10
2+	21-30	5-10
3+	31-40	10-15 or with pseudopods
4+	greater than 40	greater than 15 or with many pseudopods

If after twenty minutes no skin reaction is observed, continued testing using increments of the concentration until a reaction of 5-10 mm wheal and 10-30 mm erythema is obtained, or a concentration of 5^{-2} or 10^{-1} if using 10,000 BAU/ml extract has been tested. A positive control of histamine phosphate and a negative control of 50% v/v glycerine diluted with diluent to 5^{-2} (1:25) or 10^{-1} (1:10) dilution, should be included in interpretation of intradermal testing.[1]

INTRADERMAL TESTING - SKIN ENDPOINT TITRATION: Patient's degree of sensitivity and the initial dose of allergen to be used in immunotherapy can be quantitated using five-fold dilutions of allergenic extract for intracutaneous testing. Intracutaneously inject 0.01-0.02 ml of the test allergen to form a 4 mm diameter superficial wheal. A concentration of 0.02 BAU/ml is a safe initial dilution ("CLINICAL PHARMACOLOGY", Table 1B). When a sequence of five-fold or ten-fold dilutions of an allergen are injected, the endpoint is determined by noting the dilution that first produces a wheal and erythema (15 minutes after injection) that is 2 mm larger than wheals with erythema produced by weaker, nonreacting dilutions (5mm negative wheal). The endpoint dilution is used as a starting dose concentration for immunotherapy.

IMMUNOTHERAPY: Normally, immunotherapy can be started with 0.15 ml of the dilution of allergenic extract causing the endpoint reaction. In any allergic patient, a safe starting dose can be determined by finding the first dose by intradermal skin testing producing a 1+ reaction or the dilution producing the skin endpoint.

Increasing doses of 5-20% increments can be administered providing initial or preceding dose is tolerated without significant local reactions. The rate of increase in dosage in the early stages of treatment with highly diluted extracts is usually more rapid than the rate of increase possible with more concentrated extracts. This schedule is intended only as a guide and must be modified according to the reactivity of the individual patient. Physicians must proceed cautiously in the treatment of highly sensitive patients who develop large local or systemic reactions.

Some patients may tolerate larger doses of the allergenic extract depending on patient response.[3] Because diluted extracts lose activity on storage, the first dose from a more concentrated vial should be the same or less than the previous dose.[4,7]

Dosages progressively increase according to the tolerance of the patient at intervals of one to seven days until: (1) the patient achieves relief of symptoms; (2) induration at the site of injection is no larger than 50 mm in 36 to 48 hours; (3) a maintenance dose is reached (the largest dose tolerated by the patient that relieves symptoms without undesirable local or systemic reactions). This maintenance dose may be continued at regular intervals perennially. It may be necessary to adjust the progression of dosage downward to avoid local and constitutional reactions.[2]

The usual duration of treatment has not been established. A period of two or three years on immunotherapy constitutes an average minimum course of treatment.

SWITCHING FROM NON-STANDARDIZED TO STANDARDIZED GRASS POLLEN EXTRACT: Caution is imperative when switching from non-standardized grass pollen to Standardized Grass Pollen extracts. Standardized Grass Pollens may have equal, greater, or lesser potency than non-standardized grass pollen ("CLINICAL PHARMACOLOGY", Table 2).

Patient skin testing, utilizing side by side endpoint titration, can be used to determine the relative potency of standardized to non-standardized grass pollen extract. Based on their relative potency, a dose equipotent to the non-standardized extract can be administered. For example, a five fold dilution of

standardized extract producing the identical skin responses as the non-standardized grass pollen concentrate would require five fold reduction of dose. (If patient had been receiving 0.1 ml of non-standardized extract concentrate, then they should now receive 0.1 ml of 1:5 dilution of the Standardized Grass Pollen extract.)

Alternately, standardized extract or a mix containing Standardized Grass Pollen extract can be administered as though the patient were newly beginning immunotherapy; i.e. the patient can be skin tested to determine a safe initial dose.

HOW SUPPLIED

Standardized Grass Pollen allergenic extract concentration is expressed in BAU/ml. It is supplied in 100,000 BAU/ml and 10,000 BAU/ml in 10, 30 and 50 ml containers. Standardized Bermuda Grass is only available as 10,000 BAU/ml concentrate. Stock mixtures of Standardized Grass Pollens and mixtures of standardized and non-standardized grass pollens are available at various concentrations. Extracts in 5 ml dropper bottles are available for prick-puncture testing. To insure maximum potency for the entire dating period, all stock concentrates contain 50% v/v glycerine.

STORAGE

Store all stock concentrates and dilutions at 2-8 degrees C. Keep at this temperature during office use. The expiration date of allergenic extracts is listed on the container label. Dilutions of allergenic extracts containing less than 50% v/v glycerine are less stable than those containing at least 50% v/v glycerine. If loss of potency is suspected, potency can be checked using side by side skin testing with freshly prepared dilutions of equal concentration on individuals with known sensitivity to the allergen.

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STANDARDIZED BERMUDA GRASS POLLEN

standardized bermuda grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0063
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0063-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0063-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0063-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0063-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102226	06/13/1997	

STANDARDIZED MEADOW FESCUE GRASS POLLEN

standardized meadow fescue grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0205
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0205-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0205-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0205-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0205-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102227	06/13/1997	

STANDARDIZED ORCHARD GRASS POLLEN

standardized orchard grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0341
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0341-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0341-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0341-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0341-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102228	06/13/1997	

STANDARDIZED REDTOP GRASS POLLEN

standardized redtop grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0451
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0451-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0451-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0451-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0451-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102229	06/13/1997	

STANDARDIZED PERENNIAL RYE GRASS POLLEN

standardized perennial rye grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0452
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0452-2	5 mL in 1 VIAL, MULTI-DOSE		

2	NDC:49288-0452-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0452-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0452-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102230	06/13/1997	

STANDARDIZED TIMOTHY GRASS POLLEN

standardized timothy grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0575
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0575-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0575-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0575-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0575-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102231	06/13/1997	

STANDARDIZED KENTUCKY (JUNE) BLUEGRASS

standardized kentucky (june) bluegrass injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0277
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0277-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0277-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0277-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0277-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0277-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103421	06/13/1997	

STANDARDIZED SWEET VERNAL GRASS POLLEN

standardized sweet vernal grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0492
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

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)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0492-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0492-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0492-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0492-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103624	06/13/1997	

MIXTURE OF FOUR STANDARDIZED GRASSES

mixture of four standardized grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0232
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	25000 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	25000 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	25000 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	25000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL

Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0232-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0232-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0232-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103421	06/13/1997	

MIXTURE OF FIVE STANDARDIZED GRASSES

mixture of five standardized grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0233
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	20000 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	20000 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	20000 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	20000 [BAU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	20000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0233-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0233-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0233-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103421	06/13/1997	

MIXTURE OF SIX STANDARDIZED GRASSES

mixture of six standardized grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0234
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	16667 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	16667 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	16667 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	16667 [BAU] in 1 mL
FESTUCA PRATENSIS POLLEN (UNII: A0WFQ8P6N1) (FESTUCA PRATENSIS POLLEN - UNII:A0WFQ8P6N1)	FESTUCA PRATENSIS POLLEN	16667 [BAU] in 1 mL
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	16667 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0234-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0234-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0234-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103421	06/13/1997	

MIXTURE OF SEVEN STANDARDIZED GRASSES

mixture of seven standardized grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0235
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	14286 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	14286 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	14286 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	14286 [BAU] in 1 mL
FESTUCA PRATENSIS POLLEN (UNII: A0WFQ8P6N1) (FESTUCA PRATENSIS POLLEN - UNII:A0WFQ8P6N1)	FESTUCA PRATENSIS POLLEN	14286 [BAU] in 1 mL
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	14286 [BAU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	14286 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0235-2	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0235-3	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0235-4	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0235-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103421	06/13/1997	

MIXTURE OF EIGHT STANDARDIZED GRASSES

mixture of eight standardized grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0236
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	1250 [BAU] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	12500 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	12500 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	12500 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	12500 [BAU] in 1 mL
FESTUCA PRATENSIS POLLEN (UNII: A0WFQ8P6N1) (FESTUCA PRATENSIS POLLEN - UNII:A0WFQ8P6N1)	FESTUCA PRATENSIS POLLEN	12500 [BAU] in 1 mL
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	12500 [BAU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	12500 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0236-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0236-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0236-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102226	06/13/1997	

MIXTURE OF TWENTY-TWO STANDARDIZED AND NON-STANDARDIZED GRASSES

mixture of twenty-two standardized and non-standardized grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0240
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	455 [BAU] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	4545 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	4545 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	4545 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	4545 [BAU] in 1 mL
FESTUCA PRATENSIS POLLEN (UNII: A0WFQ8P6N1) (FESTUCA PRATENSIS POLLEN - UNII:A0WFQ8P6N1)	FESTUCA PRATENSIS POLLEN	4545 [BAU] in 1 mL
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	4545 [BAU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	4545 [BAU] in 1 mL
POA COMPRESSA POLLEN (UNII: 50HCQ1NYV5) (POA COMPRESSA POLLEN - UNII:50HCQ1NYV5)	POA COMPRESSA POLLEN	0.00227 g in 1 mL
TYPHA LATIFOLIA POLLEN (UNII: 341PDX5PLM) (TYPHA LATIFOLIA POLLEN - UNII:341PDX5PLM)	TYPHA LATIFOLIA POLLEN	0.00227 g in 1 mL
BROMUS SECALINUS POLLEN (UNII: Q4T1SJ3046) (BROMUS SECALINUS POLLEN - UNII:Q4T1SJ3046)	BROMUS SECALINUS POLLEN	0.00227 g in 1 mL
ZEA MAYS POLLEN (UNII: 74PD8J616H) (ZEA MAYS POLLEN - UNII:74PD8J616H)	ZEA MAYS POLLEN	0.00227 g in 1 mL
SECALE CEREALE POLLEN (UNII: I6KAZ8AO1O) (SECALE CEREALE POLLEN - UNII:I6KAZ8AO1O)	SECALE CEREALE POLLEN	0.00227 g in 1 mL
TRITICUM AESTIVUM POLLEN (UNII: F1KAH8374D) (TRITICUM AESTIVUM POLLEN - UNII:F1KAH8374D)	TRITICUM AESTIVUM POLLEN	0.00227 g in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	0.00227 g in 1 mL
ELYMUS REPENS POLLEN (UNII: ON2T85TA2O) (ELYMUS REPENS POLLEN - UNII:ON2T85TA2O)	ELYMUS REPENS POLLEN	0.00227 g in 1 mL
PHALARIS ARUNDINACEA POLLEN (UNII: FAY1Y90VJ9) (PHALARIS ARUNDINACEA POLLEN - UNII:FAY1Y90VJ9)	PHALARIS ARUNDINACEA POLLEN	0.00227 g in 1 mL
BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6)	BROMUS INERMIS POLLEN	0.00227 g in 1 mL
SORGHUM BICOLOR SSP. DRUMMONDII POLLEN (UNII: B43R30VP73) (SORGHUM BICOLOR SSP. DRUMMONDII POLLEN - UNII:B43R30VP73)	SORGHUM BICOLOR SSP. DRUMMONDII POLLEN	0.00227 g in 1 mL
ARRHENATHERUM ELATIUS POLLEN (UNII: B55BD1QM4Q) (ARRHENATHERUM ELATIUS POLLEN - UNII:B55BD1QM4Q)	ARRHENATHERUM ELATIUS POLLEN	0.00227 g in 1 mL

HOLCUS LANATUS POLLEN (UNII: 70O1TP6H01) (HOLCUS LANATUS POLLEN - UNII:70O1TP6H01)	HOLCUS LANATUS POLLEN	0.00227 g in 1 mL
PASCOPYRUM SMITHII POLLEN (UNII: 6AU0ZD8T1O) (PASCOPYRUM SMITHII POLLEN - UNII:6AU0ZD8T1O)	PASCOPYRUM SMITHII POLLEN	0.00227 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0240-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0240-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0240-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102226	06/13/1997	

MIXTURE OF STANDARDIZED AND NON-STANDARDIZED SOUTHERN GRASSES

mixture of standardized and non-standardized southern grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0239
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	1667 [BAU] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	16667 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	16667 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	16667 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	16667 [BAU] in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	0.0083 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0239-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0239-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0239-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102226	06/13/1997	

MIXTURE OF STANDARDIZED AND NON-STANDARDIZED INLAND GRASSES

mixture of standardized and non-standardized inland grasses injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0241
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	14286 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	14286 [BAU] in 1 mL
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	14286 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	14286 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	14286 [BAU] in 1 mL
POA COMPRESSA POLLEN (UNII: 50HCQ1NYV5) (POA COMPRESSA POLLEN - UNII:50HCQ1NYV5)	POA COMPRESSA POLLEN	0.0071 g in 1 mL
BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6)	BROMUS INERMIS POLLEN	0.0071 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0241-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0241-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0241-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103421	06/13/1997	

MIXTURE OF STANDARDIZED AND NON-STANDARDIZED SOUTHEASTERN GRASSES

mixture of standardized and non-standardized southeastern grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0243
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	3333 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	33333 [BAU] in 1 mL
PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK)	PASPALUM NOTATUM POLLEN	0.0167 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0243-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0243-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0243-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102226	06/13/1997	

MIXTURE OF STANDARDIZED AND NON-STANDARDIZED COASTAL GRASSES

mixture of standardized and non-standardized coastal grasses injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0242
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	11111 [BAU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	11111 [BAU] in 1 mL
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	11111 [BAU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	11111 [BAU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	11111 [BAU] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	11111 [BAU] in 1 mL
POA COMPRESSA POLLEN (UNII: 50HCQ1NYV5) (POA COMPRESSA POLLEN - UNII:50HCQ1NYV5)	POA COMPRESSA POLLEN	0.0056 g in 1 mL
ARRHENATHERUM ELATIUS POLLEN (UNII: B55BD1QM4Q) (ARRHENATHERUM ELATIUS POLLEN - UNII:B55BD1QM4Q)	ARRHENATHERUM ELATIUS POLLEN	0.0056 g in 1 mL
HOLCUS LANATUS POLLEN (UNII: 70O1TP6H01) (HOLCUS LANATUS POLLEN - UNII:70O1TP6H01)	HOLCUS LANATUS POLLEN	0.0056 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	0.0095 g in 1 mL
Sodium Bicarbonate (UNII: 8MDF5V39QO)	0.0024 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0242-3	10 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0242-4	30 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0242-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103421	06/13/1997	

Labeler - Antigen Laboratories, Inc. (030705628)

Establishment

Name	Address	ID/FEI	Business Operations
Antigen Laboratories, Inc.		030705628	manufacture

Revised: 8/2009 Antigen Laboratories, Inc.