TREATMENT SET TS340074 - treatment set ts340074 injection, solution
TREATMENT SET TS340153 - treatment set ts340153 injection, solution
TREATMENT SET TS340525 - treatment set ts340525 injection, solution
TREATMENT SET TS340526 - treatment set ts340526 injection, solution
Antigen Laboratories, Inc.

ALLERGENIC EXTRACTS
INDIVIDUAL TREATMENT VIAL

WARNINGS

Individual allergenic extract treatment vial is intended for use by physicians who are experienced in the administration of allergenic extracts for immunotherapy and the emergency care of anaphylaxis, or for use under the guidance of an allergy specialist. Individual allergenic extract treatment vials are not directly interchangeable with other allergenic extracts. The 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 extract to individual treatment vials should be started as though they were coming under treatment for the first time. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician's office if reaction symptoms occur. As with all allergenic extracts, severe systemic reactions may occur. In certain individuals, these reactions may be life-threatening. Patient should be observed for at least 20 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.

This product should not be injected intravenously. Deep subcutaneous routes have proven to be safe. See the warnings, precautions, adverse reactions and overdosage sections below.

DESCRIPTION

Allergenic extract in this vial is referred to as an individual treatment vial since it is designed primarily for the physician equipped to complete skin testing and supervise allergenic extract immunotherapy. The extract is sterile and intended for subcutaneous injection. The concentration of allergenic extract supplied will be based on the individual physician's prescription order and will be expressed in most cases on a weight/volume basis (or AU/ml with standardized extract) diluted either 1:10 or 1:5. Where mixtures of pollens and non-pollens have been ordered, the ingredients are listed on the final container label. To insure maximum potency for the entire dating period, dilutions will be prepared with 50% v/v glycerine unless otherwise specified.

Ingredients - Active allergens, preservative and stabilizer are noted on the Physicians Prescription Ingredients Insert enclosed with each individual allergenic extract treatment vial.

Dating Period - A twelve month dating period (expiration date) for the prescription vial will be on the container label. Extract Treatment Sets should be reordered when outdated. Government requirements include a two week holding period for sterility tests. Please allow three weeks minimum for delivery.

CLINICAL PHARMACOLOGY

The mechanisms by which immunotherapy (hyposensitization) is achieved are not completely understood. Anaphylaxis or "anaphylactic shock," and hay fever are caused by the same basic process: the production of IgE antibody, its attachment to mast cells and, on renewed contact with the same antigen explosive degranulation of the mast cells and release of mediators, which act on smooth muscle,

mucous glands, and blood vessels. With massive release there is bronchospasm, vomiting, skin rashes, edema of the nose and throat, and vascular collapse, sometimes fatal, while with more localized release one or more of these symptoms predominates, depending on the site (tissue shock organ) of exposure to the antigen.

Antigens that can trigger these reactions are known as "allergens"; they have very diverse origins but a curious similarity of molecular weight. People who suffer unduly from allergy are called "atopic"; this trait is usually inherited and has been attributed to a variety of constitutional abnormalities.

The IgE dependent degranulation of mast cells is initiated by the bridging of pairs of cell-bound IgE by antigen and terminates rapidly. Bridging results in alteration of the cell membrane, which is associated with increased energy dependent entry of calcium, alterations in phospholipid metabolism and increase of cyclic adenosine monophosphate (cyclic AMP).

The mast cell membrane is ruffled and possesses receptors both for the Fc portion of IgE and C3b. Receptors for anaphylatoxin (C3a and C5a), have been defined functionally. In addition to IgE antigen interaction and stimulation by anaphylatoxin, mast cells may be degranulated by non-immunological stimuli such as enzymes, ionophores, polycations, radio-contrast dyes and opiates. Atopic individuals develop their symptoms principally as a result of IgE-dependent processes; however, non- IgE mediated mechanisms for the release of mast cell mediators provide additional potential for recruitment of mediators.

Subsequent to activation, the secretion of granules is under cyclic nucleotide regulation. Of direct relevance is the possibility that the mast cell itself, by histamine (H^2) and prostaglandins (E^2, D^2, I^2) may increase cyclic AMP and inhibit secretion. Conversely histamine (H^1) could elevate cyclic GMP and PGF, 2 alpha lower cyclic AMP, augmenting the release of mediators. [18]

INDICATIONS AND USAGE

When the natural exposure to elevated aeroallergens produces symptoms as described under Clinical Pharmacology, specific diagnosis and therapeutic procedures are indicated. Clearly, important clues to the cause of a person's allergic condition can be gleaned from a thorough history and careful physical examination. Diagnostic tests - in vitro or in vivo - serve only to confirm the physician's suspicions or to improve investigative skills. Specific diagnosis is especially indicated when the patient's symptoms are not controlled by medication. When immunotherapy is contemplated demonstration of sensitivity to a specific allergenic extract is necessary. An orderly approach to the use of diagnostic tests usually begins with direct skin testing. [5,6,11]

THIS PRODUCT IS NOT INTENDED FOR TREATMENT OF PATIENTS WHO DO NOT MANIFEST IMMEDIATE HYPERSENSITIVITY REACTIONS TO THE ALLERGENIC EXTRACT FOLLOWING SKIN TESTING.

CONTRAINDICATIONS

There are no absolute contraindications; however, 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 previous skin testing or treatment. **IN THESE CASES BOTH THE POTENCY FOR SKIN TESTS AND THE ESCALATION OF THE TREATMENT DOSE MUST BE ADJUSTED TO THE PATIENT'S SENSITIVITY AND TOLERANCE.**

This product is not intended for the treatment of patients who do not experience allergic symptoms upon natural exposure to the allergen. At the present time there has been no demonstrated adverse effects on the fetus when allergenic extract immunotherapy is administered during gestation to pregnant women.

100,000 AU/ml standardized allergenic extract should be used by physicians with experience in maximal dose immunotherapy and treatment of anaphylaxis.

WARNINGS

Epinephrine 1:1000 should be available.

When changing immunotherapy from an unstandardized to an AU/ml standardized allergenic extract, dose adjustment, if indicated, should be based on the comparative potency of the extracts. Patient re-evaluation may be necessary.

Injections should never be given intravenously. A 5/8 inch 25 gauge needle on a sterile syringe will allow deep subcutaneous injection. Precaution of withdrawing the plunger slightly after inserting the needle is advisable to determine if a blood vessel has been entered. Proper measurement of the dose and caution in making the injection will minimize reactions. Patients should be detained for twenty to thirty minutes after injection or advised to return to the office immediately if symptoms or reactions occur.

Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and/or death.

GENERAL PRECAUTIONS

Pregnancy Category C: There are no adequate and well controlled studies in pregnant women. Allergenic extracts should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use: Doses of allergenic extracts for children are generally the same as those for adults. The maximum volume of extract tolerated without undue pain and swelling may be less for smaller individuals and therefore the maximum dose and treatment schedule must be individualized.

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.

Refrigerate at 2-8 degrees C.

Sterile solutions, vials, syringes, etc. should be used. Aseptic technique should be observed when making dilutions, skin testing, and extracts for treatment. The usual precautions in administering allergenic extracts are necessary.

A separate autoclave sterilized or disposable syringe and needle should be used for each individual patient to prevent transmission of serum hepatitis, A.I.D.S. and other infectious agents from one person to another.

The initial dilution of allergen extract, starting dose, and progression of dosage must be carefully determined on the basis of the patient's history and results of skin tests. Patients with a history of severe sensitivity and markedly positive skin tests to high dilutions of the allergen extract should be started with low doses of highly diluted extract. Pregnancy or a history of prior reactions to allergen immunotherapy dictates the need to start with small quantities of antigen.

If the first injection of the initial dilution of extract is tolerated without significant local reaction, increasing doses by 5-20% increments of that dilution may be administered. 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. Needless to say, the physician must proceed cautiously in the treatment of the highly sensitive patient who develops large local or systemic reactions.

Some patients may tolerate larger doses, but it is rarely necessary to give maintenance doses larger than 2,000 AU/ml of the standardized extract or 0.5 ml of 1:100 w/v of the unstandardized extract. Because dilute extracts tend to lose activity on storage, the first dose from a more concentrated vial, should be

the same or less than the previous dose.[1,2,3,4,16]

Immunotherapy must be given under the supervision of a physician. Before an injection is given the patient should be asked about any reaction following the previous injection to help determine the next dose. Target maintenance dose should be determined by the physician's experience and patient response to skin testing and treatment.

Dosages progressively increase thereafter 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 short of aggravating existing symptoms, systemic symptoms, or anaphylaxis. The dose should be escalated until the patient is receiving a final maintenance dose containing 2.7 to 22 u/ml or more of ragweed AgE (using Short Ragweed as example) or demonstrates untoward reactions that indicate the dose to be excessive. This maintenance dose may be continued at regular intervals perennially or achieved each year by a new, but shortened course of treatment. It may be necessary to adjust the progression of dosage downward to avoid local and constitutional reactions.

Immunotherapy of patients highly sensitive to ragweed pollen (using Short Ragweed as an example) receiving a dose of 2.7 to 46.8 units of ragweed AgE (1,000-2,000 or more AU/ml of standardized ragweed extract) was significantly more effective than placebo for (1) relieving symptoms of ragweed hay fever, (2) producing increase in serum levels of anti-ragweed IgG, (3) decrease in seasonal rises in levels of anti-ragweed IgE, (4) decrease in leukocyte histamine release from exposure to ragweed pollen extract in some patients, and (5) increase in IgG and IgA antibodies in nasal secretions. [17]

In addition to these changes in humoral antibody production, immunotherapy also effects some cellular changes. Basophils from treated subjects release less histamine in vitro and are less sensitive to the allergen (that is, higher concentrations of allergens are required to induce histamine release) than are basophils from non-treated patients. Lymphocytes from treated patients exhibit decreased proliferative response and decreased production of lymphokine in the presence of the specific allergen. A state of tolerance may be induced in the IgE producing B lymphocytes, there may be impairment in T-lymphocyte helper function, or immunotherapy may generate suppressor cells. Antigen specific suppressor cells, probably bearing histamine receptors, are generated during immunotherapy for allergy and may be partly responsible for the efficacy of this therapy. [14]

Loss of potency of aqueous pollen extracts has been recognized as a problem since shortly after the introduction of modern methods of immunotherapy. This loss of potency occurs more rapidly in saline extracts without added preservatives at high temperature and at greater extract dilutions. At concentrations of 1:100 all dilutions containing glycerin, human serum albumin, maintained extract potency within 1 logarithm (log) dilution of the original strength for 12 months; glycerin was significantly superior to all other extracts at 1, 3, and 12 months; and the deleterious effect of phenol was minimal. The deleterious effect of phenol was more marked at the higher dilutions. It was concluded that there may be marked loss of potency of dilute pollen extracts stored for periods of only two weeks under conditions which may be encountered in normal clinical practice. [12]

DOSAGE AND ADMINISTRATION

As a consequence of the discovery of IgE and the development of methods to identify and quantify anti-allergen IgE levels, interest in recent years has centered around the utilization of in vivo and in vitro diagnostic procedures. [7,9]

Patients who react to a small quantity of antigen by skin testing can be classified as highly sensitive. Those who react only to large quantities of antigen can be classified as less sensitive. It would appear that there is at least a 50,000-fold range between the most and least sensitive individuals. On the other hand, certain patients who do not appear to have elevated quantities of specific anti-allergen IgE do have positive skin tests and have symptoms of allergic rhinitis. These patients are considerably less sensitive than patients with detectable levels of specific IgE antibody. [10]

The current standard method of immunotherapy dates back to the earliest studies by Noon. As adapted for ragweed pollen extract, therapy is begun with a low dose, which has been shown to be tolerated by both experience and skin testing.

The physician who undertakes immunotherapy should be concerned with the degree of sensitivity of the patient. This can be measured by skin test, leukocyte histamine release, or anti-allergen IgE levels. Strongly positive skin tests or high initial ragweed IgE and total IgE may be risk factors for systemic reactions. Less aggressive immunotherapy schedules may be indicated for such patients. Maintenance dose potency must be established by the physician's clinical observation and experience. [10,17]

Serial fivefold or tenfold dilutions of the extract are used to make more dilute extract concentrations. Other concentrations can be prepared by appropriate dilution. In brief, the allergist can prepare any dilution of extract that is considered appropriate for the patient.

ADVERSE REACTIONS

Systemic reactions may range from mild exaggeration of the patient’s allergic symptoms to anaphylactic reactions. Very sensitive patients may show a rapid response. In some instances a severe systemic reaction with blood pressure fall and/or shock may occur. Quantitation of patient's sensitivity combined with careful early observation is essential for safe skin testing and treatment.

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

1) Local Reactions

Small amounts of erythema and swelling at the site of injection are common, the extent varying with the patient. Such 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 also indicate the possibility of a systemic reaction if dosage is increased. In such cases the dosage should be reduced to the last level not causing the reaction and maintained at this level for two or three treatments before cautiously increasing again.

Large, persistent local reactions or minor exacerbations of the patient’s allergic symptoms may be treated by local cold applications and/or the use of oral antihistamines, but they should be considered a warning of possible severe systemic reactions and the need for temporarily reduced dosages.

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

2) Systemic Reactions

With careful attention to dosage and administration, such reactions occur infrequentIy, but it must be remembered that 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 be prepared for the treatment of severe reactions.

Adverse reaction frequency data for allergenic extract administration is not available. Inherent difficulties in establishing such data are the wide variations in clinical allergy types, patient sensitivity, treatment schedules used by allergists, potency of extracts from various sources, etc.

It cannot be overemphasized that, under certain unpredictable combinations of circumstances, anaphylactic shock is always a possibility. Other possible systemic reaction symptoms are, in varying degrees of severity, fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis, and urticaria.[17,18]

OVERDOSAGE

If a systemic or anaphylactic reaction does occur, apply a tourniquet above the site of injection and inject intramuscularly or subcutaneously 0.3 to 0.5 ml of 1:1000 epinephrine-hydrochloride into the opposite arm. The dose may be repeated in 5-10 minutes if necessary. Loosen the tourniquet at least every 10 minutes.

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.

Patients unresponsive to epinephrine may be treated with theophylline. Studies on asthmatic subjects reveal that plasma concentrations of theophylline of 5 to 20 ug/ml are associated with therapeutic effects. Toxicity is particularly apparent at concentrations greater than 20 ug/ml. A loading dose of aminophylline of 5.6 mg/kg intravenously followed by 0.9 mg/kg per hour results in plasma concentrations of approximately 10 ug/ml. (Mitenko and Ogilive 1973b; Nicholoson and Chick 1973).

Other beta-adrenergic drugs such as isoproterenol, isoetharine, or albuterol may be used by inhalation. The usual dose to relieve broncho-constriction in asthma is 0.5 ml or the 0.5% solution for isoproterenol HCL; albuterol is longer acting than isoproterenol by any route of administration. The albuterol inhaler delivers approximately 90 mcg of albuterol from the mouthpiece. The usual dosage for adults and children would be two inhalations repeated every 4 to 6 hours. Isoetharine supplied in the Bronkometer unit delivers approximately 340 mcg isoetharine. The average adult dose is one to two inhalations.

Patients receiving beta-blockers may not be responsive to epinephrine or inhaled bronchodilators. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require Theophylline, low-flow oxygen, intubation and the use of life support systems. Parenteral fluid and/or plasma expanders may be utilized for treatment of shock and low flow (two liters per minute) oxygen may be utilized if indicated. Adenocorticosteroids may be administered parenterally or intravenously. 8

HOW SUPPLIED

Individual treatment sets as prescribed by the physician. The allergenic extract contains a variable number of individual doses depending on the patient's sensitivity and maximum tolerated maintenance treatment dose.

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CONTAINER LABELING

TREATMENT SET TS340074
treatment set ts340074 injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0807
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FELIS CATUS HAIR (UNII: 1564HD0N96) (FELIS CATUS HAIR - UNII:1564HD0N96)	FELIS CATUS HAIR	400 [BAU] in 1 mL
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	1000 [BAU] in 1 mL
AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3)	AMBROSIA ARTEMISIIFOLIA POLLEN	10000 [AU] in 1 mL
CARYA ALBA POLLEN (UNII: G2A764T54B) (CARYA TOMENTOSA POLLEN - UNII:G2A764T54B)	CARYA ALBA POLLEN	0.0025 g in 1 mL
DERMATOPHAGOIDES FARINAE (UNII: PR9U2YPF3Q) (DERMATOPHAGOIDES FARINAE - UNII:PR9U2YPF3Q)	DERMATOPHAGOIDES FARINAE	400 [AU] in 1 mL
DERMATOPHAGOIDES PTERONYSSINUS (UNII: 57L1Z5378K) (DERMATOPHAGOIDES PTERONYSSINUS - UNII:57L1Z5378K)	DERMATOPHAGOIDES PTERONYSSINUS	400 [AU] in 1 mL
CANIS LUPUS FAMILIARIS HAIR (UNII: 05S7L91ZTR) (CANIS LUPUS FAMILIARIS HAIR - UNII:05S7L91ZTR)	CANIS LUPUS FAMILIARIS HAIR	0.002 g in 1 mL
JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR)	JUGLANS NIGRA POLLEN	0.005 g in 1 mL
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)	ULMUS AMERICANA POLLEN	0.005 g in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	4000 [BAU] in 1 mL
IVA ANNUA VAR. ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA VAR. ANNUA POLLEN - UNII:Y2U5S5PF22)	IVA ANNUA VAR. ANNUA POLLEN	0.005 g in 1 mL
CARYA TOMENTOSA POLLEN (UNII: G2A764T54B) (CARYA TOMENTOSA POLLEN - UNII:G2A764T54B)	CARYA TOMENTOSA POLLEN	0.0025 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOL (UNII: 339NCG44TV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0807-3	10 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	10/31/1986	

TREATMENT SET TS340153

treatment set ts340153 injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0808
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARYA TOMENTOSA POLLEN (UNII: G2A764T54B) (CARYA TOMENTOSA POLLEN - UNII:G2A764T54B)	CARYA TOMENTOSA POLLEN	0.0002 g in 1 mL
CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y)	CARYA ILLINOINENSIS POLLEN	0.0002 g in 1 mL
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)	ULMUS AMERICANA POLLEN	0.01 g in 1 mL
SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G)	SALSOLA KALI POLLEN	0.01 g in 1 mL
PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK)	PLATANUS OCCIDENTALIS POLLEN	0.01 g in 1 mL
JUGLANS NIGRA POLLEN (UNII: 1BV28146ZR) (JUGLANS NIGRA POLLEN - UNII:1BV28146ZR)	JUGLANS NIGRA POLLEN	0.002 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0808-3	10 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	10/31/1986	

TREATMENT SET TS340525

treatment set ts340525 injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0809
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H)	ALTERNARIA ALTERNATA	0.00008 g in 1 mL
CANIS LUPUS FAMILIARIS HAIR (UNII: 05S7L91ZTR) (CANIS LUPUS FAMILIARIS HAIR - UNII:05S7L91ZTR)	CANIS LUPUS FAMILIARIS HAIR	0.00008 g in 1 mL
RHIZOPUS STOLONIFER (UNII: FEE198DK4Q) (RHIZOPUS STOLONIFER - UNII:FEE198DK4Q)	RHIZOPUS STOLONIFER	0.00008 g in 1 mL
DERMATOPHAGOIDES FARINAE (UNII: PR9U2YPF3Q) (DERMATOPHAGOIDES FARINAE - UNII:PR9U2YPF3Q)	DERMATOPHAGOIDES FARINAE	16 [AU] in 1 mL
DERMATOPHAGOIDES PTERONYSSINUS (UNII: 57L1Z5378K) (DERMATOPHAGOIDES PTERONYSSINUS - UNII:57L1Z5378K)	DERMATOPHAGOIDES PTERONYSSINUS	16 [AU] in 1 mL
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)	ASPERGILLUS FUMIGATUS	0.002 g in 1 mL
CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC)	CANDIDA ALBICANS	0.002 g in 1 mL
PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089)	PERIPLANETA AMERICANA	0.00008 g in 1 mL
COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS - UNII:3LN5B70U4W)	COCHLIOBOLUS SATIVUS	0.002 g in 1 mL
CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)	CLADOSPORIUM CLADOSPORIOIDES	0.00008 g in 1 mL
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	0.00008 g in 1 mL
PLEOSPORA HERBARUM (UNII: 0N3Z1P4B2W) (PLEOSPORA HERBARUM - UNII:0N3Z1P4B2W)	PLEOSPORA HERBARUM	0.00008 g in 1 mL
USTILAGO NUDA HORDEI (UNII: 9Y53ZS6I82) (USTILAGO NUDA HORDEI - UNII:9Y53ZS6I82)	USTILAGO NUDA HORDEI	0.00002 g in 1 mL
USTILAGO MAYDIS (UNII: 4K7Z7K7SWG) (USTILAGO MAYDIS - UNII:4K7Z7K7SWG)	USTILAGO MAYDIS	0.00002 g in 1 mL
USTILAGO AVENAE (UNII: YIH315U1TU) (USTILAGO AVENAE - UNII:YIH315U1TU)	USTILAGO AVENAE	0.00002 g in 1 mL
USTILAGO TRITICI (UNII: BV82OL2IZ8) (USTILAGO TRITICI - UNII:BV82OL2IZ8)	USTILAGO TRITICI	0.00002 g in 1 mL
GALLUS GALLUS FEATHER (UNII: 1FCM16V0FV) (GALLUS GALLUS FEATHER - UNII:1FCM16V0FV)	GALLUS GALLUS FEATHER	0.00067 g in 1 mL
ANAS PLATYRHYNCHOS FEATHER (UNII: 83B65P4796) (ANAS PLATYRHYNCHOS FEATHER - UNII:83B65P4796)	ANAS PLATYRHYNCHOS FEATHER	0.00067 g in 1 mL
ANSER ANSER FEATHER (UNII: 15XI414745) (ANSER ANSER FEATHER - UNII:15XI414745)	ANSER ANSER FEATHER	0.00067 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0809-3	10 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	10/31/1986	

TREATMENT SET TS340526

treatment set ts340526 injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0810
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	16 [BAU] in 1 mL
IVA ANNUA VAR. ANNUA POLLEN (UNII: Y2U5S5PF22) (IVA ANNUA VAR. ANNUA POLLEN - UNII:Y2U5S5PF22)	IVA ANNUA VAR. ANNUA POLLEN	0.002 g in 1 mL
ACER NEGUNDO POLLEN (UNII: P6K070AR8V) (ACER NEGUNDO POLLEN - UNII:P6K070AR8V)	ACER NEGUNDO POLLEN	0.00008 g in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	400 [BAU] in 1 mL
PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI)	PLANTAGO LANCEOLATA POLLEN	0.002 g in 1 mL
JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G)	JUNIPERUS VIRGINIANA POLLEN	0.002 g in 1 mL
POPULUS DELTOIDES POLLEN (UNII: 476DVV63WP) (POPULUS DELTOIDES POLLEN - UNII:476DVV63WP)	POPULUS DELTOIDES POLLEN	0.00008 g in 1 mL
CARYA ILLINOINENSIS POLLEN (UNII: PYO4JR720Y) (CARYA ILLINOINENSIS POLLEN - UNII:PYO4JR720Y)	CARYA ILLINOINENSIS POLLEN	0.00004 g in 1 mL
BETULA NIGRA POLLEN (UNII: 93963RFO1P) (BETULA NIGRA POLLEN - UNII:93963RFO1P)	BETULA NIGRA POLLEN	0.0004 g in 1 mL
FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q)	FRAXINUS AMERICANA POLLEN	0.00008 g in 1 mL
CARYA TOMENTOSA POLLEN (UNII: G2A764T54B) (CARYA TOMENTOSA POLLEN - UNII:G2A764T54B)	CARYA TOMENTOSA POLLEN	0.00004 g in 1 mL
QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK)	QUERCUS ALBA POLLEN	0.0004 g in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	0.002 g in 1 mL
KOCHIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (KOCHIA SCOPARIA POLLEN - UNII:07A108ZKW5)	KOCHIA SCOPARIA POLLEN	0.002 g in 1 mL
CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN)	CHENOPODIUM ALBUM POLLEN	0.002 g in 1 mL
AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW)	AMARANTHUS RETROFLEXUS POLLEN	0.002 g in 1 mL

AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX)	AMBROSIA TRIFIDA POLLEN	0.00008 g in 1 mL
AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3)	AMBROSIA ARTEMISIIFOLIA POLLEN	0.00008 g in 1 mL
AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L)	AMBROSIA PSILOSTACHYA POLLEN	0.00008 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0810-3	10 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	10/31/1986	

Labeler - Antigen Laboratories, Inc. (030705628)

Registrant - Antigen Laboratories, Inc. (030705628)

Establishment

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

Revised: 3/2011 Antigen Laboratories, Inc.