COTTON LINTERS - cotton linters injection, solution
JUTE - jute injection, solution
KAPOK - kapok injection, solution
ORRIS ROOT - orris root injection, solution
PYRETHRUM - pyrethrum injection, solution
LEAF TOBACCO - leaf tobacco injection, solution
Antigen Laboratories, Inc.

Allergenic Extract

WARNINGS

Allergenic extract is intended for use by, or under the guidance of, physicians who are experienced in the administration of allergenic extracts for diagnosis and/or immunotherapy and the emergency care of anaphylaxis. This extract is 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 switching from other types of extracts to Antigen Laboratories' allergenic extracts should be started as if they were undergoing treatment for the first time. Patients being switched from one lot of extract to another from the same manufacturer should have the dose reduced by 75%.

Severe systemic reactions may occur with all allergenic extracts. In certain individuals, especially in steroid-dependent/unstable asthmatics, these life-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.

This product 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. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require theophylline, oxygen, intubation and the use of life support systems. Parenteral fluid and/or plasma expanders may be utilized for treatment of shock. Adrenocorticosteroids may be administered parenterally or intravenously. Refer to "WARNINGS", "PRECAUTIONS" and "ADVERSE REACTIONS" sections below.

DESCRIPTION

Antigen Laboratories' allergenic extracts are manufactured from source material listed on the vial label. Lower concentrations (e.g. 1:50, 1:33, etc.) may be prepared either by dilution from a more concentrated stock or by direct extraction. The extract is a sterile solution containing extractables of source materials obtained from biological collecting and/or processing firms and Antigen Laboratories. All source materials are inspected by Antigen Laboratories' technical personnel in accordance with 21 CFR 680.1 (b) (1). The route of administration for immunotherapy is subcutaneous. The routes of administration for diagnostic purposes are intradermal or prick-puncture of the skin.

FOR ALLERGENIC EXTRACTS CONTAINING 50% V/V GLYCERINE AS PRESERVATIVE AND STABILIZER:

INACTIVE INGREDIENTS:

Sodium chloride…….0.95%

Sodium bicarbonate……..0.24%

Glycerine……50% (v/v)

Water for Injection……q.s. to volume

Active allergens are described by common and scientific name on the stock concentrate container label or on last page of this circular.

Food allergenic extracts may be manufactured on a weight/volume (w/v) or volume/volume (v/v) basis. Food extracts made from dried raw material are extracted at 2-10% (1:50-1:10 w/v ratio) in extracting fluid containing 50% glycerine. Slurries of juicy fruits or vegetables (prepared with a minimum amount of water for injection) are combined with an equal volume of glycerine for a ration of 1:1 volume/volume (v/v). Sodium chloride and sodium bicarbonate are added to the slurry and glycerine mixture. Fresh egg white extract is prepared by adding one part raw egg white to nine parts of extracting fluid (1:9 v/v).

Antigen E is considered the most important allergen of Short Ragweed pollen and is used for the standardization of Short Ragweed allergenic extracts. Stock mixtures containing Short Ragweed are analyzed for Antigen E content by radial immunodiffusion using Center for Biologics Evaluation and Research (CBER) references and anti-serum. Antigen E content expressed as units of Antigen E per milliliter (U/ml) is printed on container label.

CLINICAL PHARMACOLOGY

Studies indicate allergic individuals produce immunoglobulins of the IgE class in response to exposure to allergens. Subsequent exposure to the allergen 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.[3]

The mode of action of immunotherapy with allergenic extracts is still under investigation. Subcutaneous injections of increasing doses of allergenic extract into patients with allergic disease have been shown to result in both humoral and cellular changes including the production of allergen-specific IgG antibodies, the 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-lymphocyte cell responses to antigen.[10, 14, 15]

INDICATIONS AND USAGE

Allergenic extract is used for diagnostic testing and for the treatment (immunotherapy) of patients whose histories indicate that upon natural exposure to the allergen, they experience allergic symptoms. Confirmation is determined by skin testing. Diagnostic use of allergenic extracts usually begins with direct skin testing. This product is not intended for treatment of patients who do not manifest immediate hypersensitivity reactions to the allergenic extract following skin testing.

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 the underlying disease, possibly due to routine immunization. Patients who have experienced a recent myocardial infarction may not be tolerant of immunotherapy. Children with nephrotic syndrome probably should not receive injections due to immunization causing exacerbation of nephrotic disease.

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 PATIENT’S 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long term studies in animals have not been conducted with allergenic extract to determine their potential for carcinogenicity, mutagenicity or impairment of fertility.

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 extract 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.[11]

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 safety problems or specific hazards 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.[16, 17]

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.[1, 2]

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_1 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.[1]

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.[1]

Cromolyn. Cromolyn inhaled or injected prior to skin tests with allergens or degranulating agents does not alter 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 observed in patients undergoing specific immunotherapy with pollen extracts, grass pollen allergoids, mites, 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.[14] 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.[5] Other possible systemic reaction symptoms are fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis,and urticaria.[13, 14]

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 an 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 ½ 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 providing adequate epinephrine and circulatory support.[4]

Patients who have been taking beta-blockers may be unresponsive to epinephrine. Epinephrine or beta-adrenergic drugs (Alupent) may be ineffective. 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 IM 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.

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. Strongly positive skin tests may be risk factors for systemic reactions. Less aggressive immunotherapy schedules may be indicated for such patients.

Precaution is necessary when using extract mixture for skin testing. The diluting effect of individual components within a mixture may cause false negative reactions. Patients extremely sensitive to a common allergen in several components of a mixture may be more likely to experience a systemic reaction than when skin tested individually for each component.[9]

PRICK-PUNCTURE TESTING: To identify highly sensitive individuals and as a safety precaution, it is recommended that a prick-puncture test using a drop of the extract concentrate be performed prior to initiating very dilute intradermal testing. Prick-puncture testing is performed by placing a drop of extract concentrate on the skin and puncturing the skin through the drop with a small needle such as a bifurcated vaccinating needle. The most satisfactory sites on the back for skin testing are from the 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. 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 the allergen. The more sensitive the patient the higher the probability that he/she will have symptoms related to the exposure of the offending allergen. Hence, the importance of a good patient history. Less sensitive individuals can be tested intradermally with an appropriately diluted extract.

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.

SINGLE DILUTION INTRADERMAL TESTING: The surface of the upper and lower arm is the usual location for skin testing. It is important that a new, sterile, disposable syringe and needle be used for each extract tested. Intracutaneous test dilutions, five-fold or ten-fold, may be prepared from stock concentrate using physiologic saline as a diluent. (1) Start testing with the most dilute allergenic extract concentration. (2) A volume of 0.02-0.05 ml should be injected slowly into the superficial skin layers making a small bleb (superficial wheal). (3) For patients without a history of extreme sensitivity, or a negative or weakly reactive prick-puncture test, the initial dilution for skin testing should be a dilution at least 1:12,500 w/v. This initial dilution can be prepared by diluting 1:20 to 1:50 w/v (2%-5%) extracts five-fold to 5^{-4} or 1:10 w/v (10%) extracts to 5^{-5}. See "Serial Dilutions Titration Test Dilutions" chart on the next page. Dilute 1:10 w/v (10%) extracts to 10^{-3} if using ten-fold dilutions. (4) Sensitive patients with a positive prick-puncture test require a further dilution to at least 1:312,500 w/v. This dilution can be prepared by diluting 1:20 to 1:50 w/v (2% - 5%) extracts to 5^{-6} or 1:10 w/v (10%) extracts to 5^{-7} (five-fold dilutions). Ten-fold dilution to 10^{-6} of a 1:10 w/v (10%) extract would be a safe starting dilution. Size of reactions are quantitated based on size of wheal and erythema. For interpretation of skin reactions, refer to chart below. If after 20 minutes no skin reaction is observed, continue testing using increasing increments of the concentration until a reaction of 5-10 mm wheal and 11-30 mm erythema is obtained, or a concentration of 5^{-2} or 10^{-1} has been tested. A negative control, 50% glycerine diluted with diluent to 5^{-2} (1:25) or 10^{-1} (1:10) dilution and a positive control of histamine phosphate, should be tested and included in interpretation of skin reactions.[1, 13]

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

INTRADERMAL TESTING-SKIN ENDPOINT TITRATION: The allergenic extracts to which the patient is sensitive, the patient's degree of sensitivity and the dose of allergen to be used in immunotherapy can be determined through the use of intracutaneous skin tests involving progressive five-fold dilutions of allergenic extracts. Intracutaneously inject 0.01 to 0.02 ml of the test allergen to form a 4 mm diameter superficial skin wheal. For patients demonstrating a negative or weakly reactive prick-puncture skin test, an initial screening dilution of 1:12,500 w/v is safe. For patients demonstrating a positive prick-puncture skin test, an initial screening dilution of 1:312,500 w/v is safe. (See "Serial Dilution Titration Test Dilutions" chart below.) 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, non-reacting dilutions (5 mm negative wheal). The endpoint dilution is used as a starting dose concentration for immunotherapy. An endpoint dose of 0.15 ml is a safe initial dose to be followed by escalation to the optimal maximum tolerated dose for each individual.

Injections should never be given intravenously. A 5/8 inch, 25 gauge needle on a sterile syringe will allow deep subcutaneous injection.

IMMUNOTHERAPY: 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.*[6]

Some patients may tolerate larger doses of the allergenic extract depending on patient response.[7] Because diluted extract tends to lose activity in storage, the first dose from a more concentrated vial should be the same, or less than, the previous dose.[8, 12]

Dosages progressively increase according to the tolerance of the patient at intervals of one to seven days until, (1) the patient achieves relief from 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.

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.

SERIAL DILUTION TITRATION TEST DILUTIONS APPROXIMATE ALLERGENIC EXTRACT CONCENTRATION RESULTING FROM 1:5 DILUTION

Titration Number	Dilution Exponent	Weight / Volume	Allergenic Extract Concentrate				
			1:50 (2%)	1:40 (2 1/2%)	1:33 1/3 (3%)	1:20 (5%)	1:10 (10%)
No. 1	5^{-1}	1:5	1:250	1:200	1:167	1:100	1:50
No. 2	5^{-2}	1:25	1:1,250	1:1,000	1:835	1:500	1:250
No. 3	5^{-3}	1:125	1:6,250	1:5,000	1:4,175	1:2,500	1:1,250
No. 4	5^{-4}	1:625	1:31,250	1:25,000	1:20,875	1:12,500	1:6,250
No. 5	5^{-5}	1:3,125	1:156,250	1:125,000	1:104,375	1:62,500	1:31,250
No. 6	5^{-6}	1:15,625	1:781,250	1:625,000	1:521,875	1:312,500	1:156,250
No. 7	5^{-7}	1:78,125	1:3,906,250	1:3,125,000	1:2,609,375	1:1,562,500	1:781,250
No. 8	5^{-8}	1:390,625	1:19,531,250	1:15,625,000	1:13,046,875	1:7,812,500	1:3,906,250
No. 9	5^{-9}	1:1,953,125	1:97,656,250	1:78,125,000	1:65,234,375	1:39,062,500	1:19,531,250
No. 10	5^{-10}	1:9,765,625	1:488,281,250	1:390,625,000	1:326,171,875	1:195,312,500	1:97,656,250
No. 11	5^{-11}	1:48,828,125	1:2,441,406,250	1:1,953,125,000	1:1,630,859,375	1:976,562,500	1:488,281,250
No. 12	5^{-12}	1:244,140,625	1:12,207,031,250	1:9,765,625,000	1:8,154,296,875	1:4,882,812,500	1:2,441,406,250

HOW SUPPLIED

Stock concentrates are available in concentrations of 2-10% or weight/volume (w/v) of 1:50, 1:33, 1:20 or 1:10. Some juicy or liquid foods are available at 1:1 volume/volume (v/v) extraction ratio. Fresh egg white extract is available at 1:9 v/v extraction ratio.

Antigen E content of ragweed mixtures ranges from 46-166 U/ml for Ragweed Mixture (Short/Giant/Western/Southern Ragweed), 47-239 U/ml for Short/Giant/Western Ragweed Mixture, and 106-256 U/ml for Short/Giant Ragweed Mixture. Refer to container label for actual Antigen E content.

Extract (stock concentrate) is supplied in 10, 30 and 50 ml containers. 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% glycerine v/v.

STORAGE

Store all stock concentrates and dilutions at 2-8° C. Keep at this temperature during office use. The expiration date of the allergenic extracts is listed on the container label. Dilutions of the allergenic extracts containing less than 50% glycerine are less stable. 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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COTTON LINTERS

cotton linters injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0154
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
COTTON FIBER (UNII: 70LDW53ROO) (COTTON FIBER - UNII:70LDW53ROO)	COTTON FIBER	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0154-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0154-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0154-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0154-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0154-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	03/23/1974	

JUTE

jute injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0272
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CORCORUS CAPSULARIS FIBER (UNII: TVA75O7S63) (CORCORUS CAPSULARIS FIBER - UNII:TVA75O7S63)	CORCORUS CAPSULARIS FIBER	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0272-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0272-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0272-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0272-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0272-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	03/23/1974	

KAPOK

kapok injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0285
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEIBA PENTANDRA FIBER (UNII: 758Z9H9WV9) (CEIBA PENTANDRA FIBER - UNII:758Z9H9WV9)	CEIBA PENTANDRA FIBER	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0285-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0285-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0285-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0285-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0285-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	03/23/1974	

ORRIS ROOT

orris root injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0343
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

IRIS GERMANICA VAR. FLORENTINA ROOT (UNII: M30XO5X4XD) (IRIS GERMANICA VAR. FLORENTINA ROOT - UNII:M30XO5X4XD)	IRIS GERMANICA VAR. FLORENTINA ROOT	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0343-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0343-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0343-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0343-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0343-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	04/13/1992	

PYRETHRUM

pyrethrum injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0403
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRETHRUM CINERARIIFOLIUM (UNII: CGF76TP7X6) (PYRETHRUM CINERARIIFOLIUM - UNII:CGF76TP7X6)	PYRETHRUM CINERARIIFOLIUM	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0403-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0403-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0403-3	10 mL in 1 VIAL, MULTI-DOSE		

4	NDC:49288-0403-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0403-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	03/23/1974	

LEAF TOBACCO

leaf tobacco injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0581
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0581-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0581-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0581-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0581-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0581-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	04/13/1992	

ORRIS ROOT

orris root injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0344
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IRIS GERMANICA VAR. FLORENTINA ROOT (UNII: M30XO5X4XD) (IRIS GERMANICA VAR. FLORENTINA ROOT - UNII:M30XO5X4XD)	IRIS GERMANICA VAR. FLORENTINA ROOT	0.05 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49288-0344-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0344-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0344-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0344-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0344-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	03/23/1974	

LEAF TOBACCO

leaf tobacco injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0582
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	0.05 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0582-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0582-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0582-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0582-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0582-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	03/23/1974	

LEAF TOBACCO

leaf tobacco injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49288-0583
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	0.02 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.525 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.0095 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0024 g in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49288-0583-1	2 mL in 1 VIAL, MULTI-DOSE		
2	NDC:49288-0583-2	5 mL in 1 VIAL, MULTI-DOSE		
3	NDC:49288-0583-3	10 mL in 1 VIAL, MULTI-DOSE		
4	NDC:49288-0583-4	30 mL in 1 VIAL, MULTI-DOSE		
5	NDC:49288-0583-5	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102223	03/23/1974	

Labeler - Antigen Laboratories, Inc. (030705628)

Registrant - Antigen Laboratories, Inc. (030705628)

Establishment

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

Revised: 11/2009

Antigen Laboratories, Inc.