MIXED ASPERGILLUS- aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus injection, solution MIXED FEATHERS- anas platyrhynchos feather, anser anser feather, gallus gallus feather injection, solution

4 WEED MIX- amaranthus retroflexus pollen, chenopodium album pollen, plantago lanceolata pollen and xanthium strumarium pollen injection, solution 9 TREE MIX- acer saccharinum pollen, alnus rhombifolia pollen, betula lenta whole, carya ovata pollen, fraxinus americana pollen, platanus occidentalis pollen, populus alba pollen, quercus alba pollen, ulmus americana pollen injection, solution

9 TREE MIX- acer saccharinum pollen, alnus rhombifolia pollen, betula lenta whole, carya ovata pollen, fraxinus americana pollen, platanus occidentalis pollen, populus alba pollen, quercus alba pollen, ulmus crassifolia pollen injection, solution

HICKORY PECAN MIX- carya illinoinensis pollen, carya ovata pollen injection, solution

MIDWEST MOLDS- chaetomium globosum, cochliobolus sativus, gibberella zeae, mucor plumbeus, phoma exigua var. exigua, rhizopus arrhizus var. arrhizus injection, solution

MIXED MOLDS- alternaria alternata, aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus, cladosporium sphaerospermum, penicillium chrysogenum var. chrysogenum injection, solution

MIXED PENICILLIUM- penicillium chrysogenum var. chrysogenum injection, solution

MIXED RAGWEED- ambrosia artemisiifolia, ambrosia trifida pollen injection, solution

MOLD MIX 1- alternaria alternata, aspergillus niger var. niger, cladosporium sphaerospermum, cochliobolus sativus and penicillium chrysogenum var. chrysogenum injection, solution

MOLD MIX 2- aureobasidium pullulans, curvularia inaequalis, fusarium roseum, mucor plumbeus, phizopus oryzae injection, solution

FAPP MIXTURE- aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus, gibberella zeae, penicillium

chrysogenum var. chrysogenum, phoma exigua var. exigua injection, solution ALK-Abello, Inc.

Aqueous Mixtures

DIRECTIONS FOR USE OF

THERAPEUTIC ALLERGENIC EXTRACTS

WARNING

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

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 rarely result in death. Patients should be observed for 20 to 30 minutes following treatment, and emergency measures, as well as personnel trained in their use, should be immediately available in the event of a life-threatening reaction. Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk. Adverse events are to be reported to Med Watch (1-800-FDA-1088), Adverse Event Reporting , Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

This product should not be injected intravenously. Deep subcutaneous routes have proven to be safe. 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 the treatment of shock. Adrenocorticosteroids may be administered parenterally or intravenously.

Refer to WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections below.

Port Washington, NY 11050

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DESCRIPTION

Sterile therapeutic extracts are supplied in either Phenol Saline Diluent or in Diluent containing Glycerin 50% (v/v) for subcutaneous injection. Inactive ingredients may include: Sodium Chloride for isotonicity, Glycerin, and Sodium Bicarbonate as buffering agents. These products are compounded and diluted on a w/v or PNU basis. Pollens are individually extracted from pure pollen extracted in a phenol-preserved sodium bicarbonate solution. Short Ragweed and Mixed (Tall and Short) Ragweed extracts are standardized by Antigen E content and so labeled. The Antigen E content of extracts containing Short Ragweed at a concentration more dilute than a weight/volume ratio of 1:10 are obtained by calculating the Antigen E content based on the assay value of more concentrated extract. Pollen extracts are filtered aseptically and, after final packaging, they are tested for sterility and safety. Molds are individually extracted from pure powdered inactivated mold source material extracted in phenol preserved saline. Mold extracts are filtered aseptically and after final packaging are tested for sterility and safety. Molds are present in all inhabited places at all seasons of the year; they are so ubiguitous that they are prevalent at times when common allergic pollens and other inhalants are not. In the home and surroundings, molds are found in upholstered furniture, mattresses, drapes, cellar and storage room dust, woolens, leather goods,

fruits, meats, cheeses, garden soil and on plants. Spores, mycelial fragments and mold residues are thus inhaled, contacted and ingested continuously.

Miscellaneous inhalants and epidermals are individually extracted in phenol preserved saline, filtered aseptically and after final packaging are tested for sterility and safety.

CLINICAL PHARMACOLOGY

The treatment consists of the subcutaneous injection of gradually increasing doses of the allergens to which the patient is allergic. It has been demonstrated that this method of treatment induces an increased tolerance to the allergens responsible for the symptoms on subsequent exposure. The exact relationships between allergen, skinsensitizing antibody (IgE) and the blocking antibody (IgG) have not been precisely established. Clinically confirmed immunological studies have adduced evidence of the efficacy of hyposensitization therapy.

Numerous controlled studies have demonstrated the clinical efficacy of immunotherapy with cat, dust mites and some pollen extracts. Nevertheless, responses are variable, and in a few studies patients reported no appreciable benefit.

Extracts containing Short Ragweed pollen bear a labeled potency declaration in terms of Antigen E content. Numerous studies have confirmed Antigen E (AgE) as the major antigen associated with Short Ragweed pollinosis.¹ Therefore, it is essential that the physician be aware of AgE content of allergenic extract administered for hyposensitization therapy.

Some studies have indicated that for most patients a cumulative Antigen E dosage of less than 0.1 unit is not immunizing (sufficient to stimulate specific IgG antibodies).² This, however, does not suggest that 0.1 unit is a maximum tolerated dose. Most moderately sensitive patients may tolerate a dosage of ten to fifty times greater. If results with this product are unsatisfactory with exquisitely sensitive patients who cannot tolerate an immunizing dose, the physician should consider alternative therapy.

One well-controlled study demonstrated that standard immunotherapy (gradually increasing doses of antigen given subcutaneously to a maximum tolerated peak dose) using crude ragweed extract of known Antigen E potency, was significantly superior to placebo and low dose immunotherapy (0.1 units AgE cumulative dose) in amelioration of symptoms associated with ragweed hay fever. These patients received a cumulative dose of 18-350 units Antigen E (median = 84.9 units). The maximum single dose ranged from 3.7 to 46.8 units (median = 11.1 units) prior to the ragweed hay fever season.¹⁰

Patients for this study were sensitive to Ragweed Antigen E, as determined by intradermal skin testing at a dose of 0.01 units AgE/mL. A series of 24 weekly injections were administered. Forty-seven percent of the patients experienced at least one systemic reaction with an average of 1.2 systemic reactions per patient. None of the patients were able to achieve the expected maximum dose (90 units of Antigen E) in the 24 weekly injection dosage schedule.

INDICATIONS AND USAGE

Hyposensitization (injection) therapy is a treatment for patients exhibiting allergic

reactions to seasonal pollens, dust, molds, animal danders, various other inhalants, and in situations where the offending allergen cannot be avoided.

Prior to initiation of therapy, the clinical sensitivity should be established by careful evaluation of the patient's history confirmed by diagnostic skin testing. Hyposensitization should not be prescribed for sensitivities to allergens which can easily be avoided.

CONTRAINDICATIONS

A patient should not be immunized with preparations of allergens to which the patient has not demonstrated symptoms, IgE antibodies, positive skin tests, or properly controlled challenge testing. In most cases, immunotherapy is not indicated for those allergens that can be eliminated or minimized by environmental control.

Patients on beta-blockers are not candidates for immunotherapy, as they can be nonresponsive to beta-agonists that may be required to reverse a systemic reaction (also see **WARNINGS AND ADVERSE REACTIONS**).

In the presence of active symptoms such as rhinitis, wheezing, dyspnea, etc., the indication of immunotherapy must be weighed carefully against the risk of temporarily aggravating the symptoms by the injection itself.

Also, there is some evidence, although inconclusive, that routine immunizations may exacerbate autoimmune diseases.^{3,4,5} Hyposensitization should be given cautiously to patients with this predisposition. Patients with severe cardiorespiratory symptoms are at an additional risk during a systemic reaction. The physician must weigh risk to benefit in these cases.

WARNINGS

Patients should always be observed for at least 20-30 minutes after any injection. In the event of a marked systemic reaction, application of a tourniquet above the injection site and administration of 0.2 mL to 1 mL (0.01 mg/kg) of Epinephrine Injection (1:1,000) is recommended. Maximal recommended dose for children between 2 and 12 years is 0.5 mL. The tourniquet is then gradually released at 15 minute intervals. Patients under treatment with beta-blockers may be refractory to the usual dose of epinephrine.

Volume expanders and vasopressor agents may be required to reverse hypotension. Inhalation bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. In cases of respiratory obstruction, oxygen and intubation may be necessary. Life-threatening reaction unresponsive to the above may require cardiopulmonary resuscitation.

DO NOT GIVE INTRAVENOUSLY

After inserting the needle, but before injecting the dose, pull plunger of the syringe slightly. If blood returns in the syringe, discard the syringe and contents and repeat injection at another site.

Bulk concentrated extracts must be diluted for initial therapy.

Withhold allergenic extracts temporarily or reduce the dose in patients with any one of

the following conditions:

- Severe rhinitis or asthma symptoms;
- Infection or flu accompanied by fever;
- Exposure to excessive amounts of clinically relevant allergen prior to therapy.

Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk. See **PRECAUTIONS AND ADVERSE REACTIONS**.

TRANSFER OF PATIENTS

From pyridine extracted alum complexed allergenic extracts to aqueous extracts and glycerinated: In order to avoid untoward reaction, it is recommended that therapy be initiated as though patients were previously untreated. The first dose should be related to the patient's sensitivity, determined by history and confirmed by skin testing.

From unstandardized aqueous extracts to standardized aqueous extracts and glycerinated: The physician should establish the potency relationship, perhaps by comparative skin testing at equal concentration, prior to injecting the first standardized dose.

From aqueous alum precipitated or modified extracts to aqueous extracts and glycerinated: Since this subject has not been studied, it is recommended that therapy be initiated as if the patient were not previously treated.

PRECAUTIONS

INFORMATION TO PATIENTS:

Patients should be instructed to describe any active allergic symptoms such as rhinitis, wheezing, dyspnea, etc. prior to injection including any late reactions from previous administration. Patients should be instructed to remain in the office for 20 to 30 minutes after injection to monitor for adverse reactions. Also, see **ADVERSE REACTIONS** and **WARNINGS** Sections.

If the protective action of allergenic extract injections is considered essential for the patient's welfare, appropriate symptomatic therapy with antihistaminic, adrenergic or other drugs might be needed either prior to or in conjunction with the allergenic extract injections.

GENERAL:

- 1. Objective assessment of pulmonary function such as Peak Expiratory Flow Rate (PEFR) before allergen administration may be useful in unstable asthmatic to reduce the chances of exacerbation of the patient's asthma.
- 2. Store allergenic extracts between 2° and 8°C at all times, even during use.
- 3. Injections are to be given subcutaneously with the usual sterile precautions using a tuberculin syringe.
- 4. Care must be taken to avoid injecting into a blood vessel. Pull gently on syringe plunger to determine if a blood vessel has been entered (See WARNINGS).
- 5. Allergenic extracts slowly become less potent with age. During the course of treatment, it may be necessary to continue therapy with a vial of extract bearing a

later expiration date. The initial dose of the extract bearing the later expiration date should be lowered to a safe, non-reaction eliciting level which can be confirmed by comparative skin testing using end-point titration.

- 6. Use standard aseptic precautions when making dilutions. The first dose of the new extract should be reduced to at least 25% of the amount of the dosage from the previous extract.
- 7. Extracts in 50% glycerin can cause discomfort at the site of the injection.

PREGNANCY - CATEGORY C:

Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Controlled studies of hyposensitization with moderate to high doses of allergenic extracts during conception and all trimesters of pregnancy have failed to demonstrate any risk to the fetus or to the mother. However, on the basis of histamine's known ability to contract uterine muscle, the release of significant amounts of histamine from allergen exposure or hyposensitization overdose should be avoided on theoretical grounds. Therefore, allergenic extracts should be used cautiously in a pregnant woman and only if clearly needed.

PEDIATRIC USE:

Children can receive the same dose as adults, however, to minimize the discomfort associated with dose volume it may be advisable to reduce the volume of the dose by one-half and administer the injection at two different sites.

NURSING MOTHERS:

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

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

Studies in animals have not been performed.

DRUG INTERACTIONS:

Drugs can interfere with the performance of skin tests.⁶

Antihistamines: Response to mediator (histamine) released by allergens is suppressed by antihistamines. The length of suppression varies and is dependent on individual patient, type of antihistamine and length of time the patient has been on antihistamines. The duration of this suppression may be as little as 24 hours (chlorpheniramine), and can be as long as 40 days (astemizole).

Tricyclic Antidepressants: These exert a potent and sustained decrease of skin reactivity to histamine which may last for a few weeks.

Beta₂ Agonists: Oral terbutaline and parenteral ephedrine, in general, have been shown to decrease allergen induced wheal.

Dopamine: Intravenous infusion of dopamine may inhibit skin test responses.

Beta Blocking Agents: Propranolol can significantly increase skin test reactivity (See WARNINGS).

Other Drugs: Short acting steroids, inhaled beta₂ agonists, theophylline and cromolyn do not seem to affect skin test response.

ADVERSE REACTIONS

Anaphylaxis and deaths following the injection of mite and other extracts have been reported by The British Committee on Safety in Medicine.⁷ Fatalities from immunotherapy in the United States since 1945 have been extensively reviewed by Lockey, R. F., et al⁸ and more recently by Reid, M. J. et al.⁹

With careful attention to dosage and administration, such reactions occur infrequently, 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.

Local: Reactions at the site of injection may be immediate or delayed. Immediate wheal and erythema reactions are ordinarily of little consequence; but if very large, may be the first manifestation of a systemic reaction. If large local reactions occur, the patient should be observed for systemic symptoms for which treatment is outlined below.

Delayed reactions start several hours after injection with local edema, erythema, itching or pain. They are usually at their peak at 24 hours and usually require no treatment. Antihistamine drugs may be administered orally.

The next therapeutic dose should be reduced to the dose which did not elicit a reaction, and subsequent doses increased more slowly; i.e., use of intermediate dilutions.

Systemic: Systemic reactions are characterized by one or more of the following symptoms: Sneezing, mild to severe generalized urticaria, itching other than at the injection site, extensive or generalized edema, wheezing, asthma, dyspnea, cyanosis, tachycardia, lacrimation, marked perspiration, cough, hypotension, syncope and upper airway obstruction. Symptoms may progress to shock and death. Patients should always be observed for at least 20 to 30 minutes after any injection. Volume expanders and vasopressor agents may be required to reverse hypotension. Inhalational bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. Severe airway obstruction, unresponsive to bronchodilator, may require tracheal intubation and use of oxygen. In the event of a marked systemic reaction, application of a tourniquet above the injection site and the administration of 0.2 mL to 1 mL of Epinephrine Injection (1:1,000) are recommended. Maximal recommended dose for children under 2 years of age is 0.3 mL. Maximal recommended dose for children between 2 and 12 years of age is 0.5 mL. The tourniquet should not be left in place without loosening for 90 seconds every 15 minutes.

The next therapeutic injection of extract should be reduced to the dose which did not elicit a reaction, and subsequent doses increased more slowly; i.e., use of intermediate dilutions.

OVERDOSAGE

Signs and symptoms of overdose are typically local and systemic reactions. For a description and management of overdose reactions, refer to "Adverse Reaction" section above.

DOSAGE AND ADMINISTRATION

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

When diluting bulk extracts, use of Sterile Diluent for Allergenic Extracts or Sterile Diluent for Allergenic Extracts Normal Saline with HSA (albumin saline) is recommended. Dilutions should be made with sterile disposable syringes using aseptic technique. Commonly, 10 fold dilutions are used to achieve a desired concentration for initiation and continuation of immunotherapy. For example, transferring 0.5 mL of a 10,000 PNU/mL extract into 4.5 mL of diluent will yield 5 mL of extract at 1,000 PNU/mL. For weight volume products, a 1:100 w/v dilution may be prepared from a 1:10 w/v by transferring 0.5 mL of the 1:10 w/v to 4.5 mL of diluent. Prepare as many additional serial dilutions as necessary to reach the appropriate concentration.

Starting dose for immunotherapy is related directly to a patient's sensitivity as determined by carefully executed skin testing. Degree of sensitivity can be established by determination of D_{50} .¹¹ A general rule is to begin at 1/10 of the dose that produces sum of erythema of 50 mm (approximately a 2+ positive skin test reaction).

For example, if a patient exhibits a 2+ intradermal reaction to 1 AU/mL, the first dose should be no higher than 0.05 mL of 0.1 AU/mL. Dosage may be increased by 0.05 mL each time until 0.5 mL is reached, at which time the next 10-fold more concentrated dilution can be used, beginning with 0.05 mL, if no untoward reaction is observed.

Interval between doses in the early stages of immunotherapy is no more than once to twice a week, and may gradually be increased to once every two weeks. Generally, maintenance injections may be given as infrequently as once every two weeks to once a month.

Injections are given subcutaneously, preferably in the arm. It is advantageous to give injections in alternate arms and routinely in the same area. In some patients, a local tolerance to the allergen may develop thus preventing a possible severe local reaction.

Formal stability studies for diluted and undiluted forms of unstandardized extracts have not been performed; therefore, it is recommended that minimal amounts of the concentrate be diluted so that the diluted product is used up within a relatively short period of time; i.e., preferably not more than four weeks.

PRE-SEASONAL METHOD OF TREATMENT

Treatment of hay fever by the pre-seasonal method should be started 6-10 weeks prior to the usual onset of symptoms. Therapy should be started early enough to permit a graduated series of doses at 2-7 day intervals. It is recommended that the larger doses be spaced 5-7 days apart.

Some physicians continue therapy into or through the season by repeating a reduced or MAINTENANCE dose at weekly or biweekly intervals. If during the season, hay fever symptoms develop, relief may be provided by giving supplemental treatment. If the last

dose was well-tolerated and not more than 2 weeks has elapsed since it was given, this dose may be given again and repeated every 4 to 7 days.

PERENNIAL TREATMENT

The patient's tolerance to the offending pollen or pollens is first established by the injection of a series of graduated doses as outlined in the PRE-SEASONAL METHOD, not necessarily given pre-seasonally, since perennial therapy may be begun at any time. After completion of the ascending series of injections, from 1/4 to 1/2 of the highest well-tolerated dose is continued at 2 to 3 week intervals throughout the year. Shortly before the usual onset of symptoms (4 to 5 weeks prior to the season) the interval between injections is shortened and the dosage is gradually increased, according to the Pre-Seasonal schedule, until maximum well-tolerated dose is again attained. This top dose should be reached just before the usual onset of symptoms at which time the treatment is discontinued. If patient's symptoms persist, therapy may be continued at a reduced dosage level, usually 1/4 to 1/2 of the top dose.

DOSAGE ADJUSTMENTS

For Products Containing Short Ragweed.

In transferring patients from unstandardized to standardized product, the physician should establish the potency relationships, perhaps by comparative skin testing, prior to injecting the first standardized dose.

AgE is important in adjusting dosage of Short Ragweed extracts to accurately transfer a patient from older extracts to fresher material. In such cases, the dosage of AgE should be considered in addition to the W/V dilution or protein nitrogen units. Antigen E concentration continuously declines in Short Ragweed Pollen extracts at a rate that varies with the formulation of the product. Aqueous extracts retain Antigen E potency less effectively than glycerin 50% (v/v) extracts. These differences are reflected in the expiration date declared on the vial. The continuous decline should be considered. Also, where ragweed is a component of an allergen mixture, clinical response to the other components must be considered in adjustment of dosage based on AgE content alone. The usual course of immunotherapy is three to five years.

Caution: A small percent of individuals allergic to Short Ragweed are more sensitive to minor antigens such as Ra3 Ra5 than AgE. There is no correlation between the amount of these antigens and either AgE or PNU content.

NOTE: For extracts of Short Ragweed or equal part mixture of Short and Tall Ragweed refer to AgE dosage schedule. The AgE content for those products is indicated on the vial label. The physician may use the formula below to determine the AgE dosage for each injection.

AgE dosage can be monitored by using the following formula:

W/V compounded products:

Labeled AgE X Dose (mL) = dose in AgE

PNU compounded products:

<u>Labeled AgE/mL</u> X dose in PNU = dose in AgE

Labeled PNU/mL

HOW SUPPLIED

- 1. Concentrate in multiple dose vials:
- 2. Sterile Diluent for Allergenic Extracts (Phenol Saline) is supplied in vials of 4.5 mL, 9.0 mL, 30 mL and 100 mL.

10 mL and 50 mL, single antigens or specified mixtures, potency expressed in PNU/mL (up to and including 100,000 PNU/mL) or W/V (up to and including 1:10 W/V), aqueous or in 50% glycerin, to be diluted prior to use. 1:10 w/v short ragweed extracts contain \geq 300 units/mL of AgE.

STORAGE: To maintain stability of allergenic extracts, proper storage conditions are essential. Bulk concentrates and diluted extracts are to be stored at 2° to 8° C even during use. Bulk or diluted extracts are not to be frozen. Do not use after the expiration date shown on the vial label.

REFERENCES

- 1. Norman, P.S. *et al:* Immunotherapy of hayfever with ragweed antigen E. Comparisons with whole pollen extract and placebo. *J. Allergy* <u>42</u>:93, 1968.
- 2. Van Metre, T.E. *et al:* A controlled study of the effectiveness of the Rinkel method of immunotherapy for ragweed pollen hayfever. *J. Allergy Clin. Immunol.* <u>65</u>:288, 1980.
- 3. Umetsu, D.T. *et al:* Serum sickness triggered by anaphylaxis: a complication of immunotherapy. *J. Allergy Clin. Immunol.* <u>76</u>:713, 1985.
- 4. Phannphak, P. and Kohler, P.F.: Onset of polyarteritis nodosa during allergic hyposenitization treatment. *Am. J. Med.* <u>68</u>:479, 1980.
- 5. Kohler, P.F.: Immune complexes and allergic disease. In: Middleton *et al:* <u>Allergy</u> <u>Principles and Practice 3rd Ed.</u> St. Louis: CV Mosby, 1988:167.
- 6. Bousquet, J.: In vivo methods for the study of allergy: skin test, techniques, and interpretation. In: Middleton *et al:* <u>Allergy Principles and Practice 3rd Ed.</u> St. Louis: CV Mosby, 1988:167.
- 7. Committee on the Safety of Medicines. CSM update: desensitising vaccines. *Brit Med. J.* <u>293</u>:948,1986.
- 8. Lockey, R.F. *et al:* Fatalities from immunotherapy (IT) and skin testing (ST). *J. Allergy Clin. Immunol.* <u>79</u>:660, 1987.
- 9. Reid, M.J. *et al:* Survey of fatalities from skin testing and immunotherapy. *1985-1989. J. Allergy Clin. Immunol.*;<u>92</u>:6, 1993.
- 10. Van Metre, T.E. *et al:* A controlled study of the effectiveness of the Rinkel method and the current standard method of immunotherapy for ragweed pollen hayfever. *J. Allergy Clin. Immunol.* <u>66</u>:500, 1980.
- 11. Turkeltaub, P.C., Rastogi, S.C., Baer, H., et al: A standardized quantitative skin-test assay of allergen potency and stability: studies on the allergen dose-response curve and effect of wheal, erythema, and patient selection on assay results, *J. Allergy Clin. Immunol.* <u>70</u>:343, 1982.

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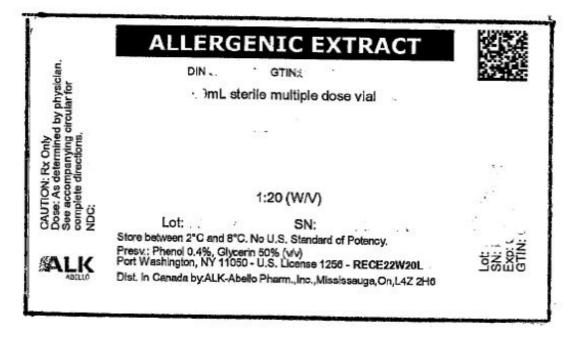
ALK-Abelló Pharmaceuticals, Inc.

#35-151 Brunel Road Mississauga, Ontario Canada L4Z 2H6

PRINCIPAL DISPLAY PANEL

ALLERGENIC EXTRACT

mL sterile multiple dose vial



MIXED ASPERGILLUS

aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus injection, solution

Product Information							
Product Type NON-STANDARDIZED ALLERGENIC Item Code (Source) NDC:0268-8035							
Route of Administration SUBCUTANEOUS							
Active Ingredient/Active	Majaty						
Active Ingredient/Active	Molety						
Ingre	dient Name		Basis of Strengt	h Strength			
ASPERGILLUS NIGER VAR. NIGER VAR. NIGER - UNII:9IOA40ANG6)	(UNII: 9IOA40ANG6) (ASPERGILLUS NIC	GER	ASPERGILLUS NIGER VAR. NIGER	40000 [PNU] in 1 mL			
ASPERGILLUS REPENS (UNII: SQ8 UNII:SQ89E6LOME)	9E6LOME) (ASPERGILLUS REPENS -		ASPERGILLUS REPENS	40000 [PNU] in 1 mL			
ASPERGILLUS FLAVUS VAR. ORYZAE (UNII: Q6Z8UK5R3G) (ASPERGILLUS FLAVUS VAR. ORYZAE - UNII:Q6Z8UK5R3G) (ASPERGILLUS VAR. ORYZAE - UNII:Q6Z8UK5R3G) (IN L MARCHARDON - UNII:Q6Z8							
FLAVUS VAR. ORYZAE - UNII:Q6Z8U	K5R3G)		VAR. ORYZAE	in 1 mL			

Inactive Ingre	edients					
	Ingredient Name			Strength		
SODIUM CHLORID	0.009 g ir	1 mL				
SODIUM BICARBO	0.0027 g	in 1 mL				
PHENOL (UNII: 339	0.004 mL in 1 mL					
HYDROCHLORIC ACID (UNII: QTT17582CB)						
SODIUM HYDROX	DE (UNII: 55X04QC32I)					
Packaging						
# Item Code	Package Description	Marketing Date	Start	Marketing End Date		
1 NDC:0268-8035- 50	53 mL in 1 VIAL; Type 0: Not a Combination Product					
магкетіпд	Information					
Marketing Category	Application Number or Monograph Citation	Marketin Dat		Marketing End Date		
BLA	BLA103753	01/01/1965		05/24/2023		

MIXED FEATHERS anas platyrhynchos feather, a	nser anser feather, gallus gallus	s feat	her injection, solut	on
Product Information				
Froduct miormation				
Product Type	NON-STANDARDIZED ALLERGENIC	Item	Code (Source)	NDC:0268-8041
Route of Administration	SUBCUTANEOUS			
Active Ingredient/Active	Moiety			
Ingre	dient Name		Basis of Strengt	n Strength
GALLUS GALLUS FEATHER (UNII: UNII: 1FCM16V0FV)	1FCM16V0FV) (GALLUS GALLUS FEATH	ER -	GALLUS GALLUS FEATHER	20000 [PNU] in 1 mL
ANAS PLATYRHYNCHOS FEATHE PLATYRHYNCHOS FEATHER - UNII:83	. , .		ANAS PLATYRHYNCHO FEATHER	S 20000 [PNU] in 1 mL
ANSER ANSER FEATHER (UNII: 15 UNII:15XI414745)	XI414745) (ANSER ANSER FEATHER -		ANSER ANSER FEATHE	R 20000 [PNU] in 1 mL
Inactive Ingredients				
-				

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Pa	ackaging						
#	ltem Code	Рас	ckage Description		eting Start Date		eting End Date
1	NDC:0268-8041- 10	10.5 mL in 1 V Product	IAL; Type 0: Not a Combination				
2	NDC:0268-8041- 50	53 mL in 1 VIA Product	L; Type 0: Not a Combination				
Μ	larketing	Informat	ion				
	Marketing Category	Applicat	tion Number or Monograph Citation	Mark	eting Start Date	Marl	ceting End Date
BL	A	BLA103753		01/01/1	965	05/24/2	023
-	WEED MIX naranthus retro	-	ı, chenopodium album pollen	, plantag	go lanceolata	pollen a	and
a	nthium struma	rium pollen ir	njection, solution				
Ρ	roduct Infor						
-	roduct mon	mation					
P	roduct Type	mation	NON-STANDARDIZED ALLERGENIC	ltem	Code (Sourc	e) ND	C:0268-8003
			NON-STANDARDIZED ALLERGENIC SUBCUTANEOUS	ltem	Code (Sourc	e) ND	C:0268-8003
	roduct Type			ltem	Code (Sourc	e) ND	C:0268-8003
R	roduct Type oute of Admini	stration	SUBCUTANEOUS	ltem	Code (Sourc	e) ND	C:0268-8003
R	roduct Type	istration ient/Active	SUBCUTANEOUS Moiety	Item			
R(A(roduct Type oute of Admini c tive Ingredi NTHIUM STRUM	ent/Active Ingre	SUBCUTANEOUS Moiety dient Name N (UNII: 2QOF601J1M) (XANTHIUM	Item	Basis of St XANTHIUM STR	rength	Strength
R A X S T	roduct Type oute of Admini ctive Ingredi NTHIUM STRUM RUMARIUM POLLE	ent/Active Ingre IARIUM POLLE N - UNII:2QOF60	SUBCUTANEOUS Moiety dient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M)	Item	Basis of Sti XANTHIUM STRI POLLEN	rength	Strength 40000 [PNU in 1 mL
R A X X S T PL	roduct Type oute of Admini ctive Ingredi NTHIUM STRUM RUMARIUM POLLE	ent/Active Ingre IARIUM POLLE N - UNII:2QOF60 OLATA POLLE	SUBCUTANEOUS Moiety dient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: DO87T1U2CI) (PLANTAGO	Item	Basis of St XANTHIUM STR	r ength UMARIUM	Strength 40000 [PNU
R A ST PL LA	roduct Type oute of Admini ctive Ingredi ANTHIUM STRUM RUMARIUM POLLE ANTAGO LANCE NCEOLATA POLLE	istration ient/Active ingre IARIUM POLLE N - UNII:2QOF60 OLATA POLLEI N - UNII:DO87T1 LBUM POLLEN	SUBCUTANEOUS Moiety dient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: DO87T1U2CI) (PLANTAGO		Basis of St XANTHIUM STRI POLLEN PLANTAGO	r ength UMARIUM OLLEN	Strengtl 40000 [PNU in 1 mL 40000 [PNU in 1 mL
R A ST PL LA CH PC	roduct Type oute of Admini ctive Ingredi ANTHIUM STRUM RUMARIUM POLLE ANTAGO LANCE NCEOLATA POLLEI HENOPODIUM AL	ent/Active Ingre IARIUM POLLE N - UNII:2QOF60 OLATA POLLEI N - UNII:DO87T1 BUM POLLEN (X5NCN) ROFLEXUS PO	SUBCUTANEOUS Moiety edient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: D087T1U2CI) (PLANTAGO LU2CI) (UNII: 098LKX5NCN) (CHENOPODIU DLLEN (UNII: 73B14PX5FW) (AMARAM	MALBUM	Basis of St XANTHIUM STRI POLLEN PLANTAGO LANCEOLATA PO CHENOPODIUM	rength UMARIUM OLLEN ALBUM	Strength 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU
R A S T PL C H R E	roduct Type oute of Admini ctive Ingredi anthium strum rumarium polle Antago Lance NCEOLATA POLLE HENOPODIUM AL DELEN - UNII:098LK MARANTHUS RET TROFLEXUS POLL	istration ient/Active ingre iarium polle N - UNII:2QOF60 OLATA POLLEI N - UNII:DO87T1 BUM POLLEN (X5NCN) ROFLEXUS PO EN - UNII:73B14	SUBCUTANEOUS Moiety edient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: D087T1U2CI) (PLANTAGO LU2CI) (UNII: 098LKX5NCN) (CHENOPODIU DLLEN (UNII: 73B14PX5FW) (AMARAM	MALBUM	Basis of Str XANTHIUM STR POLLEN PLANTAGO LANCEOLATA PO CHENOPODIUM POLLEN AMARANTHUS	rength UMARIUM OLLEN ALBUM	Strengtl 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU
R A ST PL LA CH PC AN RE	roduct Type oute of Admini ctive Ingredi ANTHIUM STRUM RUMARIUM POLLE ANTAGO LANCE NCEOLATA POLLEI HENOPODIUM AL DILLEN - UNII:098LK MARANTHUS RET	ent/Active Ingre Ingre ARIUM POLLE N - UNII:2QOF60 OLATA POLLEI N - UNII:DO87T1 BUM POLLEN (X5NCN) ROFLEXUS PO EN - UNII:73B14	SUBCUTANEOUS Moiety edient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: DO87T1U2CI) (PLANTAGO LU2CI) (UNII: 098LKX5NCN) (CHENOPODIU DLLEN (UNII: 73B14PX5FW) (AMARAN PX5FW)	MALBUM	Basis of Str XANTHIUM STR POLLEN PLANTAGO LANCEOLATA PO CHENOPODIUM POLLEN AMARANTHUS	rength UMARIUM OLLEN ALBUM POLLEN	Strengtl 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL
	roduct Type oute of Admini ctive Ingredi ANTHIUM STRUM RUMARIUM POLLE ANTAGO LANCE NCEOLATA POLLE HENOPODIUM AL OLLEN - UNII:098LK MARANTHUS RET TROFLEXUS POLLI	istration ient/Active Ingre IARIUM POLLE N - UNII:2QOF60 OLATA POLLEI N - UNII:73B14	SUBCUTANEOUS Moiety dient Name N (UNII: 2QOF601J1M) (XANTHIUM 01J1M) N (UNII: DO87T1U2CI) (PLANTAGO LU2CI) (UNII: 098LKX5NCN) (CHENOPODIU DLLEN (UNII: 73B14PX5FW) (AMARAN PX5FW)	MALBUM	Basis of Str XANTHIUM STR POLLEN PLANTAGO LANCEOLATA PO CHENOPODIUM POLLEN AMARANTHUS	rength UMARIUM OLLEN ALBUM	Strengtl 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL
R A ST PL C H R E	roduct Type oute of Admini ctive Ingredi ANTHIUM STRUM RUMARIUM POLLE ANTAGO LANCE NCEOLATA POLLE HENOPODIUM AL DILEN - UNII:098LK MARANTHUS RET TROFLEXUS POLLI	ent/Active Ingre IARIUM POLLE N - UNII:2QOF60 OLATA POLLEI N - UNII:DO87T1 BUM POLLEN (X5NCN) ROFLEXUS PO EN - UNII:73B14 edients Ing CID (UNII: QTT1	SUBCUTANEOUS Moiety edient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: DO87T1U2CI) (PLANTAGO LU2CI) (UNII: 098LKX5NCN) (CHENOPODIU DLLEN (UNII: 73B14PX5FW) (AMARAM PX5FW) redient Name	MALBUM	Basis of Str XANTHIUM STR POLLEN PLANTAGO LANCEOLATA PO CHENOPODIUM POLLEN AMARANTHUS	rength UMARIUM OLLEN ALBUM POLLEN	Strengtl 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL
R ST PL LA CHC AN RE	roduct Type oute of Admini ctive Ingredi ANTHIUM STRUM RUMARIUM POLLE ANTAGO LANCE NCEOLATA POLLE HENOPODIUM AL OLLEN - UNII:098LK MARANTHUS RET TROFLEXUS POLLI MARANTHUS RET TROFLEXUS POLLI	istration ient/Active ingre IARIUM POLLE N - UNII:2QOF60 OLATA POLLEI N - UNII:DO87TI BUM POLLEN (X5NCN) ROFLEXUS PO EN - UNII:73B14 idients ing CID (UNII: QTTI DE (UNII: 55X04	SUBCUTANEOUS Moiety edient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: DO87T1U2CI) (PLANTAGO LU2CI) (UNII: 098LKX5NCN) (CHENOPODIU DLLEN (UNII: 73B14PX5FW) (AMARAM PX5FW) redient Name 17582CB) QC32I)	MALBUM	Basis of Stu XANTHIUM STRI POLLEN PLANTAGO LANCEOLATA PA CHENOPODIUM POLLEN AMARANTHUS RETROFLEXUS	rength UMARIUM OLLEN ALBUM POLLEN Streng	Strengt 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL
R A ST PLA CH PC AN RE In SC SC	roduct Type oute of Admini ctive Ingredi ANTHIUM STRUM RUMARIUM POLLE ANTAGO LANCE NCEOLATA POLLEI HENOPODIUM AL DILLEN - UNII:098LK MARANTHUS RET TROFLEXUS POLLI	istration ient/Active Ingre IARIUM POLLE N - UNII:2QOF60 OLATA POLLEI N - UNII:2QOF60 OLATA POLLEI N - UNII:2QOF60 OLATA POLLEI STOR STOR STOR EN - UNII:2QOF60 OLATA POLLEI N - UNII:2QOF60 OLATA POLLEI STOR STOR STOR STOR STOR STOR STOR STOR	SUBCUTANEOUS Moiety edient Name N (UNII: 2QOF601J1M) (XANTHIUM D1J1M) N (UNII: D087T1U2CI) (PLANTAGO LU2CI) (UNII: 098LKX5NCN) (CHENOPODIU DLLEN (UNII: 73B14PX5FW) (AMARAM PX5FW) redient Name L7582CB) QC32I) ZU8X)	MALBUM	Basis of Str XANTHIUM STR POLLEN PLANTAGO LANCEOLATA PO CHENOPODIUM POLLEN AMARANTHUS	rength UMARIUM OLLEN ALBUM POLLEN Streng	Strengt 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL 40000 [PNU in 1 mL

Packaging

Ham Cade 4

Marketing Start Marketing End

#	item Coue	Package Description	Date	Date
1	NDC:0268-8003- 50	53 mL in 1 VIAL; Type 0: Not a Combination Product		
M	larketing l	nformation		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BL	A	BLA103753	01/01/1965	

9 TREE MIX

acer saccharinum pollen, alnus rhombifolia pollen, betula lenta whole, carya ovata pollen, fraxinus americana pollen, platanus occidentalis pollen, populus alba pollen, quercus alba pollen, ulmus americana pollen injection, solution

Product Information						
Product Type	NON-STANDARDIZED ALLERGENIC	ltem Code (Source)	NDC:0268-8020			
Route of Administration	SUBCUTANEOUS					

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ALNUS RHOMBIFOLIA POLLEN (UNII: 7X8HL8GRTM) (ALNUS RHOMBIFOLIA POLLEN - UNII:7X8HL8GRTM)	ALNUS RHOMBIFOLIA POLLEN	40000 [PNU] in 1 mL			
FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q)	FRAXINUS AMERICANA POLLEN	40000 [PNU] in 1 mL			
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)	ULMUS AMERICANA POLLEN	40000 [PNU] in 1 mL			
BETULA LENTA WHOLE (UNII: 41A3V2257T) (BETULA LENTA WHOLE - UNII:41A3V2257T)	BETULA LENTA WHOLE	40000 [PNU] in 1 mL			
ACER SACCHARINUM POLLEN (UNII: 95447163DG) (ACER SACCHARINUM POLLEN - UNII:95447163DG)	ACER SACCHARINUM POLLEN	40000 [PNU] in 1 mL			
CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798)	CARYA OVATA POLLEN	40000 [PNU] in 1 mL			
QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK)	QUERCUS ALBA POLLEN	40000 [PNU] in 1 mL			
POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII: VU8C8SB23P)	POPULUS ALBA POLLEN	40000 [PNU] in 1 mL			
PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK)	PLATANUS OCCIDENTALIS POLLEN	40000 [PNU] in 1 mL			

Inactive Ingredients					
Ingredient Name	Strength				
HYDROCHLORIC ACID (UNII: QTT17582CB)					
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL				
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL				
SODIUM HYDROXIDE (UNII: 55X04QC32I)					

Packaging # Item Code Package Description	
# Item Code Package Description	
	Marketing Start Marketing End Date Date
NDC:0268-8020- 5053 mL in 1 VIAL; Type 0: Not a Combinatio Product	on
Marketing Information	
Marketing Application Number or Monog Category Citation	raph Marketing Start Marketing End Date Date
BLA BLA103753	01/01/1965
Product Information	
Product Information Product Type NON-STANDARDIZED ALLER	RGENIC Item Code (Source) NDC:0268-8021
Product Information	RGENIC Item Code (Source) NDC:0268-8021
Product Information Product Type NON-STANDARDIZED ALLER Route of Administration SUBCUTANEOUS	RGENIC Item Code (Source) NDC:0268-8021 Basis of Strength Streng
Product Information Product Type NON-STANDARDIZED ALLER Route of Administration SUBCUTANEOUS Active Ingredient/Active Moiety Ingredient Name ALNUS RHOMBIFOLIA POLLEN (UNII: 7X8HL8GRTM) (ALNUS R	Basis of Strength Streng
Product Information Product Type NON-STANDARDIZED ALLER Route of Administration SUBCUTANEOUS Active Ingredient/Active Moiety	Basis of Strength Streng RHOMBIFOLIA ALNUS RHOMBIFOLIA 0.1 g in 1 mL
Product Information Product Type NON-STANDARDIZED ALLER Route of Administration SUBCUTANEOUS Active Ingredient/Active Moiety Ingredient Name ALNUS RHOMBIFOLIA POLLEN (UNII: 7X8HL8GRTM) (ALNUS R POLLEN - UNII:7X8HL8GRTM) FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUR POLLEN - UNII:G684LX721Q) ULMUS CRASSIFOLIA POLLEN (UNII: G82398SD3I) (ULMUS CR	Basis of StrengthStrengRHOMBIFOLIAALNUS RHOMBIFOLIA0.1 gPOLLENin 1 mLUS AMERICANAFRAXINUS AMERICANA0.1 gPOLLENin 1 mL
Product Information Product Type NON-STANDARDIZED ALLER Route of Administration SUBCUTANEOUS Active Ingredient/Active Moiety Ingredient Name ALNUS RHOMBIFOLIA POLLEN (UNII: 7X8HL8GRTM) (ALNUS R POLLEN - UNII:7X8HL8GRTM) FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINU POLLEN - UNII:G684LX721Q) ULMUS CRASSIFOLIA POLLEN (UNII: G82398SD3I) (ULMUS CF POLLEN - UNII:G82398SD3I) BETULA LENTA WHOLE (UNII: 41A3V2257T) (BETULA LENTA W	Basis of StrengthStrengRHOMBIFOLIAALNUS RHOMBIFOLIA0.1 gPOLLENin 1 mLUS AMERICANAFRAXINUS AMERICANA0.1 gPOLLENPOLLENin 1 mLRASSIFOLIAULMUS CRASSIFOLIA0.1 gin 1 mLPOLLENin 1 mL
Product Information Product Type NON-STANDARDIZED ALLER Route of Administration SUBCUTANEOUS Active Ingredient/Active Moiety Ingredient Name ALNUS RHOMBIFOLIA POLLEN (UNII: 7X8HL8GRTM) (ALNUS R POLLEN - UNII:7X8HL8GRTM) FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINU	Basis of StrengthStrengRHOMBIFOLIAALNUS RHOMBIFOLIA0.1 gPOLLENPOLLENin 1 mLUS AMERICANAFRAXINUS AMERICANA0.1 gPOLLENVLMUS CRASSIFOLIA0.1 gRASSIFOLIAULMUS CRASSIFOLIA0.1 gPOLLENBETULA LENTA WHOLE0.1 gIn 1 mLIn 1 mL
Product Information Product Type NON-STANDARDIZED ALLER Route of Administration SUBCUTANEOUS Active Ingredient/Active Moiety Ingredient Name ALNUS RHOMBIFOLIA POLLEN (UNII: 7X8HL8GRTM) (ALNUS R POLLEN - UNII:7X8HL8GRTM) FRAXINUS AMERICANA POLLEN (UNII: 6684LX721Q) (FRAXINU POLLEN - UNII:6684LX721Q) ULMUS CRASSIFOLIA POLLEN (UNII: 682398SD3I) (ULMUS CR POLLEN - UNII:682398SD3I) BETULA LENTA WHOLE (UNII: 41A3V2257T) (BETULA LENTA W UNII:41A3V2257T) ACER SACCHARINUM POLLEN (UNII: 95447163DG) (ACER SAC	Basis of StrengthStrengRHOMBIFOLIAALNUS RHOMBIFOLIA0.1 gPOLLENPOLLENin 1 mLUS AMERICANAFRAXINUS AMERICANA0.1 gPOLLENVLMUS CRASSIFOLIA0.1 gRASSIFOLIAULMUS CRASSIFOLIA0.1 gMHOLE -BETULA LENTA WHOLE0.1 gCCHARINUMACER SACCHARINUM0.1 gin 1 mLNI mL

POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN -UNII:VU8C8SB23P) PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK)

Inactive Ingredients					
Ingredient Name	Strength				
ingreatent italie	Stichigth				

0.1 g in 1 mL

0.1 g in 1 mL

POPULUS ALBA POLLEN

OCCIDENTALIS POLLEN

PLATANUS

PH	IENOL (UNII: 339N	ICG44TV)		0.004 mL	in 1 mL			
sc	SODIUM CHLORIDE (UNII: 451W47IQ8X) 0.009 g in 1 mL							
SC	SODIUM HYDROXIDE (UNII: 55X04QC32I)							
SODIUM BICARBONATE (UNII: 8MDF5V39QO) 0.0027 g in 1 mL								
Packaging								
#	ltem Code	Package Description	Marketing Date		Marketing End Date			
1	NDC:0268-8021- 50	53 mL in 1 VIAL; Type 0: Not a Combination Product						
Μ	larketing I	nformation						
	Marketing Category	Application Number or Monograph Citation	Marketin Dat	-	Marketing End Date			
BL	A	BLA103753	01/01/1965					

carya illinoinensis pollen, cary	a ovata pollen injection, solution				
Product Information					
Product Type	NON-STANDARDIZED ALLERGENIC	ltem Co	de (Source)	NDC:	0268-8029
Route of Administration	SUBCUTANEOUS				
Active Ingredient/Active	Moiety				
-	redient Name		Basis of Stre	nath	Strongt
•	JN9R2798) (CARYA OVATA POLLEN -		CARYA OVATA PO	-	0.1 g in 1 mL
CARYA ILLINOINENSIS POLLEN POLLEN - UNII:PYO4JR720Y)	(UNII: PYO4JR720Y) (CARYA ILLINOINENS	IS	CARYA ILLINOINEN POLLEN	ISIS	0.1 g in 1 mL
Inactive Ingredients					
Ing	gredient Name		Str	engtl	h
HYDROCHLORIC ACID (UNII: QTT	17582CB)				
PHENOL (UNII: 339NCG44TV)			0.004 mL in 1	mL	
SODIUM BICARBONATE (UNII: 8M	1DF5V39QO)		0.0027 g in 1 r	nL	
SODIUM CHLORIDE (UNII: 451W4	7IQ8X)		0.009 g in 1 m	L	
SODIUM HYDROXIDE (UNII: 55X0	4QC32I)				
Packaging					
Daalcaning					

Item Code Package Description Marketing Start Date Date

NDC.0360 0030 E2 ml in 1 VIAL. Time O. Nat a Combination

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
BLA	BLA103753	01/01/1965					

MIDWEST MOLDS

chaetomium globosum, cochliobolus sativus, gibberella zeae, mucor plumbeus, phoma exigua var. exigua, rhizopus arrhizus var. arrhizus injection, solution

Pr	oduct Infor	mation					
Pr	oduct Type		NON-STANDARDIZED ALLERGENI	C Iter	n Code (Sour	ce)	NDC:0268-8039
Ro	ute of Admini	stration	SUBCUTANEOUS				
Ac	tive Ingredi	ent/Active	Moiety				
		Ingre	dient Name		Basis o Strengt	-	Strength
	CHLIOBOLUS S II:3LN5B70U4W)	ATIVUS (UNII: 3	3LN5B70U4W) (COCHLIOBOLUS S	ATIVUS -	COCHLIOBOLU SATIVUS	S	20000 [PNU] in 1 mL
	AETOMIUM GLO II:5016WB8B8A)	BOSUM (UNII:	5016WB8B8A) (CHAETOMIUM GLO)BOSUM -	CHAETOMIUM GLOBOSUM		20000 [PNU] in 1 mL
	BBERELLA ZEAE II:T9GHE8H4RX)	(UNII: T9GHE8I	H4RX) (GIBBERELLA ZEAE -		GIBBERELLA ZI	EAE	20000 [PNU] in 1 mL
	COR PLUMBEU II:D7401PWY6E)	S (UNII: D7401F	WY6E) (MUCOR PLUMBEUS -		MUCOR PLUMB	EUS	20000 [PNU] in 1 mL
	oma exigua va Gua - Unii:8jag4		III: 8JAG41IE4M) (PHOMA EXIGUA V	/AR.	PHOMA EXIGUA EXIGUA	VAR.	20000 [PNU] in 1 mL
	IZOPUS ARRHIZ II:8476849N1Y)	US (UNII: 84768	349N1Y) (RHIZOPUS ARRHIZUS -		RHIZOPUS ARR	HIZUS	20000 [PNU] in 1 mL
Ina	active Ingre	dients					
		Ing	redient Name			Stre	ength
HY	DROCHLORIC A	CID (UNII: QTT)	.7582CB)				
PH	ENOL (UNII: 3391	NCG44TV)			0.004 m	L in 1 r	nL
	DIUM BICARBO	-			0.0027 g		
	DIUM CHLORIDI				0.009 g	in 1 ml	L
SO	DIUM HYDROXII	DE (UNII: 55X04	QC32I)				
	ickaging						
	ickaging Item Code	Pac	kage Description	Mark	eting Start Date	Ма	rketing End Date

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
BLA	BLA103753	01/01/1965	05/24/2023				

MIXED MOLDS

alternaria alternata, aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus, cladosporium sphaerospermum, penicillium chrysogenum var. chrysogenum injection, solution

Product Information	on					
Product Type		NON-STANDARDIZED ALLERGENIC	lter	n Code (Source)	NDC	:0268-8046
Route of Administrati	ion	SUBCUTANEOUS				
Active Ingredient/	Active	Moiety				
	Ingrea	lient Name		Basis of Stren	gth	Strength
ALTERNARIA ALTERNATA UNII:52B29REC7H)	(UNII: 52	B29REC7H) (ALTERNARIA ALTERNATA	4 -	ALTERNARIA ALTERNA	ATA	10000 [PNU] in 1 mL
CLADOSPORIUM SPHAER SPHAEROSPERMUM - UNII:F		IUM (UNII: P87YCA1U8R) (CLADOSP(I8R)	ORIUM	CLADOSPORIUM SPHAEROSPERMUM		10000 [PNU in 1 mL
ASPERGILLUS NIGER VAR VAR. NIGER - UNII:9IOA40AI		(UNII: 9IOA40ANG6) (ASPERGILLUS 1	NIGER	ASPERGILLUS NIGER NIGER	VAR.	10000 [PNU in 1 mL
ASPERGILLUS REPENS (UUNII:SQ89E6LOME)	JNII: SQ89	9E6LOME) (ASPERGILLUS REPENS -		ASPERGILLUS REPEN	S	10000 [PNU in 1 mL
ASPERGILLUS FLAVUS VAR. ORYZAE - UN		ZAE (UNII: Q6Z8UK5R3G) (ASPERGIL K5R3G)	LUS	ASPERGILLUS FLAVU ORYZAE	s var.	10000 [PNU in 1 mL
ASPERGILLUS TERREUS UNII:QBN8K7055X)	(UNII: QB	N8K7055X) (ASPERGILLUS TERREUS	-	ASPERGILLUS TERRE	US	10000 [PNU in 1 mL
		R. CHRYSOGENUM (UNII: 3Y1PE1G CHRYSOGENUM - UNII:3Y1PE1GCIG)	CIG)	PENICILLIUM CHRYSOGENUM VAR CHRYSOGENUM		10000 [PNU in 1 mL
Inactive Ingredient	ts					
	-	redient Name		St	rengt	:h
		7582CB)		0.004 mal in 1		
PHENOL (UNII: 339NCG44 SODIUM BICARBONATE	-			0.004 mL in 1		
SODIUM BICARBONATE	-			0.0027 g in 1 0.009 g in 1 r		
SODIUM HYDROXIDE (UN				0.009 g 111 1	116	
	557.04					
Packaging						
# Item Code	Pac	kage Description	Mark	eting Start M Date		ting End ate

	NDC:0268-8046- 10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
	NDC:0268-8046- 50	53 mL in 1 VIAL; Type 0: Not a Combination Product		
Μ	arketing	Information		
	Marketing	Application Number or Monograph	Marketing Start	Marketing End
	Category	Citation	Date	Date

MIXED MOLDS

Inactivo Ingradiante

alternaria alternata, aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus, cladosporium sphaerospermum, penicillium chrysogenum var. chrysogenum, penicillium chrysogenum var. chrysogenum injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:0268-8047
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H)	ALTERNARIA ALTERNATA	20000 [PNU] in 1 mL			
CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R)	CLADOS PORIUM SPHAEROS PERMUM	20000 [PNU] in 1 mL			
ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6)	ASPERGILLUS NIGER VAR. NIGER	20000 [PNU] in 1 mL			
ASPERGILLUS REPENS (UNII: SQ89E6LOME) (ASPERGILLUS REPENS - UNII:SQ89E6LOME)	ASPERGILLUS REPENS	20000 [PNU] in 1 mL			
ASPERGILLUS FLAVUS VAR. ORYZAE (UNII: Q6Z8UK5R3G) (ASPERGILLUS FLAVUS VAR. ORYZAE - UNII:Q6Z8UK5R3G)	ASPERGILLUS FLAVUS VAR. ORYZAE	20000 [PNU] in 1 mL			
ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X)	ASPERGILLUS TERREUS	20000 [PNU] in 1 mL			
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	20000 [PNU] in 1 mL			

mactive ingredients				
Ingredient Name	Strength			
HYDROCHLORIC ACID (UNII: QTT17582CB)				
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL			
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL			
SODIUM HYDROXIDE (UNII: 55X04QC32I)				

Pa	Packaging						
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:0268-8047- 10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product					
2	NDC:0268-8047- 50	53 mL in 1 VIAL; Type 0: Not a Combination Product					
M	larketing	Information					
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
BL	A	BLA103753	01/01/1965	05/24/2023			

MIXED MOLDS

alternaria alternata, aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus, cladosporium sphaerospermum, penicillium chrysogenum var. chrysogenum, penicillium chrysogenum var. chrysogenum injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:0268-8048
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H)	ALTERNARIA ALTERNATA	40000 [PNU] in 1 mL			
CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII: P87YCA1U8R)	CLADOS PORIUM SPHAEROS PERMUM	40000 [PNU] in 1 mL			
ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6)	ASPERGILLUS NIGER VAR. NIGER	40000 [PNU] in 1 mL			
ASPERGILLUS REPENS (UNII: SQ89E6LOME) (ASPERGILLUS REPENS - UNII:SQ89E6LOME)	ASPERGILLUS REPENS	40000 [PNU] in 1 mL			
ASPERGILLUS FLAVUS VAR. ORYZAE (UNII: Q6Z8UK5R3G) (ASPERGILLUS FLAVUS VAR. ORYZAE - UNII:Q6Z8UK5R3G)	ASPERGILLUS FLAVUS VAR. ORYZAE	40000 [PNU] in 1 mL			
ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X)	ASPERGILLUS TERREUS	40000 [PNU] in 1 mL			
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	40000 [PNU] in 1 mL			

Inactive Ingredients						
Ingredient Name	Strength					
HYDROCHLORIC ACID (UNII: QTT17582CB)						
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL					
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL					
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL					

sc		DE (UNII: 55X04	QC32I)						
D -									
Pā	ackaging			Maula		Chart	Max	d . .	Fad
#	Item Code	Pac	kage Description	магк	Date	Start	Mar	Da	ng End te
1	NDC:0268-8048- 50	53 mL in 1 VIA Product	L; Type 0: Not a Combination						
Μ	arketing	Informat	ion						
	Marketing Category	Applica	tion Number or Monograph Citation	Ма	rketin Dat	g Start	Ma		ing End Ite
BL		BLA103753		01/01/			05/24		
		1							
Μ	IXED PENI	CILLIUM							
be	nicillium chryso	ogenum var.	chrysogenum injection, solu	ition					
Ρ	roduct Infor	mation							
Pr	oduct Type		NON-STANDARDIZED ALLERGENIC	lter	n Cod	e (Sourc	e) 🛚	NDC:0	268-8052
Ro	oute of Admini	stration	SUBCUTANEOUS						
A	ctive Ingredi	ent/Active	Moiety						
		Ingre	dient Name		Bas	sis of St	rengt	h s	Strength
PE (PE	NICILLIUM CHRY	YSOGENUM VAR.	AR. CHRYSOGENUM (UNII: 3Y1PE CHRYSOGENUM - UNII:3Y1PE1GCIO	1GCIG) G)	CHRYS	ILLIUM SOGENUM SOGENUM	VAR.		0000 [PNU n 1 mL
In	active Ingre	diants							
	active mgre		redient Name				Stre	nath	
НΥ	DROCHLORIC A	-					0010		
	IENOL (UNII: 3391					0.004 mL	in 1 m	۱L	
sc	DIUM BICARBO	NATE (UNII: 8M	DF5V39QO)			0.0027 g	in 1 m	L	
sc	DIUM CHLORID	E (UNII: 451W47	/IQ8X)			0.009 g i	n 1 mL		
SC	DIUM HYDROXI	DE (UNII: 55X04	QC32I)						
Pa	ackaging								
#	ltem Code	Pa	ckage Description	Mark	eting Date	Start	Ма	rketi Da	ng End
1			IAL; Type 0: Not a Combination		Dute			Da	
	10 NDC:0268-8052-	Product 53 mL in 1 VIA	L; Type 0: Not a Combination						
2		Product							
2	50	Product							

Marketing		ion						
Category	Applica	tion Number or Monograp Citation	h №	1ark	eting Start Date		Marketing End Date	
BLA	BLA103753			01/19	965	05/24/20	23	
MIXED PEN	ICILLIUM							
penicillium chrys	ogenum var.	chrysogenum injection, so	lution					
Product Infor	mation							
Product Type		NON-STANDARDIZED ALLERGEN		tem	Code (Sour	(e) NDC	2:0268-8053	
Route of Admin	istration	SUBCUTANEOUS						
Active Ingred	ient/Active	Moiety						
	Ingre	dient Name			Basis of St	rength	Strength	
		AR. CHRYSOGENUM (UNII: 3Y1) CHRYSOGENUM - UNII:3Y1PE1GO		'с	ENICILLIUM HRYSOGENUM HRYSOGENUM		40000 [PNU in 1 mL	
Inactive Ingre	dients							
		redient Name				Strengt	th	
HYDROCHLORIC A	CID (UNII: QTT	17582CB)						
PHENOL (UNII: 339	NCG44TV)				0.004 mL	in 1 mL		
SODIUM BICARBO	NATE (UNII: 8M	IDF5V39QO)			0 0027 a	in 1 mL		
		• •			0.0027 y			
SODIUM CHLORID	E (UNII: 451W4				0.0027 g			
SODIUM CHLORID SODIUM HYDROXI		7IQ8X)						
SODIUM HYDROXI		7IQ8X)						
sodium hydroxi Packaging	DE (UNII: 55X04	7IQ8X)	Ma			n 1 mL Marke	ting End	
Packaging # Item Code	DE (UNII: 55X04 Pa	7IQ8X) 4QC32I)	Ma		0.009 g	n 1 mL Marke	-	
SODIUM HYDROXI Packaging # Item Code 1 NDC:0268-8053- 10	DE (UNII: 55X04 Pa 10.5 mL in 1 \ Product	riQ8X) AQC32I) ckage Description	Ma		0.009 g	n 1 mL Marke	-	
SODIUM HYDROXI Packaging # Item Code 1 NDC:0268-8053-10 2 NDC:0268-8053-	Pa 10.5 mL in 1 V Product 53 mL in 1 VIA	7IQ8X) 4QC32I) ckage Description /IAL; Type 0: Not a Combination	Ma		0.009 g	n 1 mL Marke	-	
SODIUM HYDROXI Packaging # Item Code 1 NDC:0268-8053-10 2 NDC:0268-8053-50	Pa 10.5 mL in 1 V Product 53 mL in 1 VIA Product	/IQ8X) AQC32I) Ckage Description /IAL; Type 0: Not a Combination L; Type 0: Not a Combination	Ma		0.009 g	n 1 mL Marke	-	
SODIUM HYDROXI Packaging # Item Code 1 NDC:0268-8053-10 NDC:0268-8053-20	Pa 10.5 mL in 1 V Product 53 mL in 1 VIA Product	/IQ8X) AQC32I) Ckage Description /IAL; Type 0: Not a Combination L; Type 0: Not a Combination		D	0.009 g	n 1 mL Marke D	-	

MIXED RAGWEED

Product Infor	mation					
Product Type		NON-STANDARDIZED ALLERGENIC	Item	n Code (Sourc	e) NDC:0268-8	8059
Route of Admini	stration	SUBCUTANEOUS				
Active Ingredi	ent/Active	Moiety				
	Ingre	dient Name		Basis of Strength	Strond	th
AMBROSIA ARTEM · UNII:9W34L2CQ9A)		: 9W34L2CQ9A) (AMBROSIA ARTEN	IISIIFOLIA	AMBROSIA ARTEMISIIFOLIA	40000 [PNL in 1 mL	[ו
AMBROSIA TRIFID - UNII:KU1V1898XX)	A POLLEN (UNI	I: KU1V1898XX) (AMBROSIA TRIFID	A POLLEN	AMBROSIA TRIFI POLLEN	DA 40000 [PNU in 1 mL	[ו
Inactive Ingre						
		redient Name			Strength	
		.7582CB)		0.004 mal	in 1 and	
PHENOL (UNII: 3391 SODIUM BICARBO				0.004 mL 0.0027 g		
SODIUM CHLORID				0.0027 g		
SODIUM HYDROXI						
Packaging						
# Item Code	Pa	kage Description		eting Start Date	Marketing E Date	nd
1 NDC:0268-8059- 10	10.5 mL in 1 V Product	IAL; Type 0: Not a Combination				
2 NDC:0268-8059- 50	53 mL in 1 VIA Product	L; Type 0: Not a Combination				
	Informat	ion				
Marketing	mormat					End
Marketing Marketing Category		tion Number or Monograph Citation	Mar	keting Start Date	Marketing E Date	

MIXED RAGWEED

ambrosia artemisiifolia, ambrosia trifida pollen injection, solution

Product Information								
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:0268-8060					
Route of Administration	SUBCUTANEOUS							

		Ingredient Name		Basis Stren		Strengt	
	ROSIA ARTEM 9W34L2CQ9A)	ISIIFOLIA (UNII: 9W34L2CQ9A) (AMBROSIA ARTEM	ISIIFOLIA -	AMBROSIA ARTEMISIIFO	-	0.1 g in 1 mL	
	ROSIA TRIFID KU1V1898XX)	A POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA	A POLLEN -	AMBROSIA T POLLEN	RIFIDA	0.1 g in 1 mL	
Inad	ctive Ingre	dients					
		Ingredient Name			Strengt	th	
HYDF	ROCHLORIC A	CID (UNII: QTT17582CB)					
	NOL (UNII: 3391	NCG44TV)		0.004 mL	in 1 mL		
PHEN				0.0027 g in 1 mL			
	IUM BICARBO	NATE (UNII: 8MDF5V39QO)					
50DI 50DI	IUM CHLORID	NATE (UNII: 8MDF5V39QO) E (UNII: 451W47IQ8X) DE (UNII: 55X04QC32I)		0.009 g in	1 mL		
SODI SODI SODI	IUM CHLORID	E (UNII: 451W47IQ8X)		0.009 g in			
sodi sodi sodi	IUM CHLORID IUM HYDROXI	E (UNII: 451W47IQ8X)	Marketin Dat	0.009 g in g Start	Marke	ting End Date	
SODI SODI SODI Pac # I	IUM CHLORID IUM HYDROXI Kaging Item Code	E (UNII: 451W47IQ8X) DE (UNII: 55X04QC32I)		0.009 g in g Start	Marke	ting End Date	
SODI SODI SODI Pac # I 1	IUM CHLORID IUM HYDROXI Kaging Item Code	E (UNII: 451W47IQ8X) DE (UNII: 55X04QC32I) Package Description 10.5 mL in 1 VIAL; Type 0: Not a Combination		0.009 g in g Start	Marke	-	
SODI SODI SODI Pac # I 1 NE 10 2 NE	IUM CHLORID IUM HYDROXI Kaging Item Code	E (UNII: 451W47IQ8X) DE (UNII: 55X04QC32I) Package Description 10.5 mL in 1 VIAL; Type 0: Not a Combination Product 53 mL in 1 VIAL; Type 0: Not a Combination		0.009 g in g Start	Marke	-	
SODI SODI SODI # 1 1 10 2 50	IUM CHLORID IUM HYDROXI Kaging Item Code DC:0268-8060- DC:0268-8060-	E (UNII: 451W47IQ8X) DE (UNII: 55X04QC32I) Package Description 10.5 mL in 1 VIAL; Type 0: Not a Combination Product 53 mL in 1 VIAL; Type 0: Not a Combination		0.009 g in g Start	Marke	-	
SODI SODI SODI # I 1 10 2 10 50	IUM CHLORID IUM HYDROXI Kaging Item Code DC:0268-8060- DC:0268-8060-	E (UNII: 451W47IQ8X) DE (UNII: 55X04QC32I) Package Description 10.5 mL in 1 VIAL; Type 0: Not a Combination Product 53 mL in 1 VIAL; Type 0: Not a Combination Product	Dat	0.009 g in g Start	Marke	-	

MOLD MIX 1

alternaria alternata, aspergillus niger var. niger, cladosporium sphaerospermum, cochliobolus sativus and penicillium chrysogenum var. chrysogenum injection, solution

Product Information								
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:0268-8064					
Route of Administration	SUBCUTANEOUS							

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	20000 [PNU] in 1 mL			
COCHLIOBOLUS SATIVUS (UNII: 3LN5B70U4W) (COCHLIOBOLUS SATIVUS -		20000 [PNU]			

UN	III:3LN5B70U4W)				coen	LIOBOLOS	SALIVUS	in 1 mL
	.TERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - III:52B29REC7H)				ALTERNARIA ALTERNAT		ERNATA	20000 [PNL in 1 mL
	SPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER AR. NIGER - UNII:9IOA40ANG6)				ASPERGILLUS NIGI NIGER		IGER VAR.	20000 [PNL in 1 mL
	CLADOSPORIUM SPHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOSPORIUM SPHAEROSPERMUM - UNII:P87YCA1U8R)					OS PORIUM EROS PERM		20000 [PNL in 1 mL
In	active Ingre	dients						
		Ingredi	ent Name				Streng	th
ΗY	DROCHLORIC A	CID (UNII: QTT17582	CB)					
PH	IENOL (UNII: 339	NCG44TV)				0.004 mL	in 1 mL	
SO	DIUM BICARBO	NATE (UNII: 8MDF5V	39QO)			0.0027 g	in 1 mL	
50	ODIUM CHLORIDE (UNII: 451W47IQ8X) 0.009 g in 1 mL							
30			/			-		
		DE (UNII: 55X04QC32				-		
so	DIUM HYDROXI							
so								
so	DIUM HYDROXI	DE (UNII: 55X04QC32		Mark	ceting Date	Start		eting End Date
so Pa	ackaging Item Code	DE (UNII: 55X04QC32 Packag	21)	Mark	-			-
so Pa # 1	ackaging Item Code NDC:0268-8064- 10	DE (UNII: 55X04QC32 Packag 10.5 mL in 1 VIAL; T Product	21) Je Description	Mark	-			-
so Pa #	ackaging Item Code NDC:0268-8064- 10 NDC:0268-8064-	DE (UNII: 55X04QC32 Packag 10.5 mL in 1 VIAL; T Product 53 mL in 1 VIAL; Typ	21) Je Description Type 0: Not a Combination	Mark	-			-
SC # 1 2	ACKaging Item Code NDC:0268-8064- 10 NDC:0268-8064- 50	DE (UNII: 55X04QC32 Packag 10.5 mL in 1 VIAL; T Product 53 mL in 1 VIAL; Typ	21) Je Description Type 0: Not a Combination De 0: Not a Combination	Mark	-			-
sc # 1 2	ACKaging Item Code NDC:0268-8064- 10 NDC:0268-8064- 50	DE (UNII: 55X04QC32 Packag 10.5 mL in 1 VIAL; T Product 53 mL in 1 VIAL; Typ Product Information	21) Je Description Type 0: Not a Combination De 0: Not a Combination		Date	g Start	Mark	-

MOLD MIX 1

alternaria alternata, aspergillus niger var. niger, cladosporium sphaerospermum, cochliobolus sativus and penicillium chrysogenum var. chrysogenum injection, solution

Product Information					
Product Type	NON-STANDARDIZ ED ALLERGENIC	ltem	Code (Source)	NDC	:0268-8065
Route of Administration	SUBCUTANEOUS				
Active Ingredient/Active	Moiety				
Ingre	dient Name		Basis of Streng	th	Strength
PENICILLIUM CHRYSOGENUM V	AR. CHRYSOGENUM (UNII: 3Y1PE1GCIO	-)	PENICILLIUM CHRYSOGENUM VAR.		40000 [PNU] in 1 mL
(PENICILLIUM CHRYSOGENUM VAR.	CHRYSOGENUM - UNII:3Y1PE1GCIG)		CHRYSOGENUM		

UNII:52B29REC7H)	RNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNA	ATA -	ALTERNAR	IA ALTERNATA	40000 [PNU in 1 mL
ASPERGILLUS NIG VAR. NIGER - UNII:91	ER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLU: OA40ANG6)	5 NIGER	AS PERGIL NIGER	LUS NIGER VAR.	40000 [PNL in 1 mL
	PHAEROSPERMUM (UNII: P87YCA1U8R) (CLADOS - UNII:P87YCA1U8R)	PORIUM	CLADOS PO S PHAEROS		40000 [PNL in 1 mL
Inactive Ingre	dients				
	Ingredient Name			Streng	th
HYDROCHLORIC A	CID (UNII: QTT17582CB)				
PHENOL (UNII: 339	NCG44TV)		0.0	04 mL in 1 mL	
SODIUM BICARBO	NATE (UNII: 8MDF5V39QO)		0.0	027 g in 1 mL	
SODIUM CHLORID	E (UNII: 451W47IQ8X)		0.0	09 g in 1 mL	
SODIUM HYDROXI	DE (UNII: 55X04QC32I)				
Packaging # Item Code	Package Description		eting Sta		eting End
			Date	L	Date
1 NDC:0268-8065- 50	53 mL in 1 VIAL; Type 0: Not a Combination Product				
• 50	Product				
• 50					
• 50	Product	Мат	keting S Date		eting End Date
Marketing	Product Information Application Number or Monograph	Ma 1 01/01/	Date		Date
Marketing Marketing Category	Product Information Application Number or Monograph Citation		Date		Date
Marketing Marketing Category	Product Information Application Number or Monograph Citation BLA103753		Date		Date
Marketing Marketing Category BLA	Product Information Application Number or Monograph Citation BLA103753	01/01/	Date 1965	05/24/20	Date 023
Marketing Marketing Category BLA	Product Information Application Number or Monograph Citation BLA103753 2 ullulans, curvularia inaequalis, fusarium ro	01/01/	Date 1965	05/24/20	Date 023

Product Information								
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:0268-8068					
Route of Administration	SUBCUTANEOUS							

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK)	AUREOBASIDIUM PULLULANS VAR. PULLUTANS	20000 [PNU] in 1 mL	
CURVULARIA INAEQUALIS (UNII: W042YAB8JC) (CURVULARIA INAEQUALIS - UNII:W042YAB8JC)	CURVULARIA INAEQUALIS	20000 [PNU] in 1 mL	
GIBBERELLA ZEAE (UNII: T9GHE8H4RX) (GIBBERELLA ZEAE - UNII:T9GHE8H4RX)	GIBBERELLA ZEAE	20000 [PNU] in 1 mL	
MUCOR PLUMBEUS (UNII: D7401PWY6E) (MUCOR PLUMBEUS - UNII:D7401PWY6E)	MUCOR PLUMBEUS	20000 [PNU] in 1 mL	

Inactive Ingre	dients			
	Ingredient Name		Strength	
HYDROCHLORIC A	CID (UNII: QTT17582CB)			
PHENOL (UNII: 339	NCG44TV)	0.004	mL in 1 mL	
SODIUM BICARBO	NATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL		
SODIUM CHLORID	E (UNII: 451W47IQ8X)	0.009	g in 1 mL	
SODIUM HYDROXI	DE (UNII: 55X04QC32I)			
Packaging				
# Item Code	Package Description	Marketing Starl		
	Package Description 10.5 mL in 1 VIAL; Type 0: Not a Combination Product	Marketing Starl Date	: Marketing End Date	
1 NDC:0268-8068- 10	10.5 mL in 1 VIAL; Type 0: Not a Combination		-	
 NDC:0268-8068- 10 NDC:0268-8068- 	10.5 mL in 1 VIAL; Type 0: Not a Combination Product 53 mL in 1 VIAL; Type 0: Not a Combination			
 NDC:0268-8068- 10 NDC:0268-8068- 50 	10.5 mL in 1 VIAL; Type 0: Not a Combination Product 53 mL in 1 VIAL; Type 0: Not a Combination			
 NDC:0268-8068- 10 NDC:0268-8068- 50 	10.5 mL in 1 VIAL; Type 0: Not a Combination Product 53 mL in 1 VIAL; Type 0: Not a Combination Product		Date	

MOLD MIX 2

aureobasidium pullulans, curvularia inaequalis, fusarium roseum, mucor plumbeus, phizopus oryzae injection, solution

Product Information					
Product Type	NON-STANDARDIZED ALLERGENIC	Item	Code (Source)	NDC	:0268-8069
Route of Administration	SUBCUTANEOUS				
··· · · · · · · · ·					
Active Ingredient/Active	моюту				
Ingre	dient Name		Basis of Streng	yth	Strength
AUREOBASIDIUM PULLULANS VA (AUREOBASIDIUM PULLULANS VAR.	R. PULLUTANS (UNII: D1A2NG69CK) PULLUTANS - UNII:D1A2NG69CK)		AUREOBASIDIUM PULLULANS VAR. PULLUTANS		40000 [PNU in 1 mL
CURVULARIA INAEQUALIS (UNII: V UNII:W042YAB8JC)	10042YAB8JC) (CURVULARIA INAEQUALIS	-	CURVULARIA INAEQUA	ALIS	40000 [PNU in 1 mL
GIBBERELLA ZEAE (UNII: T9GHE8 UNII:T9GHE8H4RX)	H4RX) (GIBBERELLA Z EAE -		GIBBERELLA Z EAE		40000 [PNU in 1 mL
MUCOR PLUMBEUS (UNII: D7401F UNII:D7401PWY6E)	WY6E) (MUCOR PLUMBEUS -		MUCOR PLUMBEUS		40000 [PNU in 1 mL
RHIZOPUS ARRHIZUS (UNII: 84768 UNII:8476849N1Y)	349N1Y) (RHIZOPUS ARRHIZUS -		RHIZOPUS ARRHIZUS	5	40000 [PNU in 1 mL

Ir	nactive Ingre	dients			
		Ingredient Name			Strength
H	YDROCHLORIC A	CID (UNII: QTT17582CB)			
Pł	HENOL (UNII: 339N	ICG44TV)		0.004 mL	in 1 mL
s	ODIUM BICARBOI	NATE (UNII: 8MDF5V39QO)		0.0027 g	in 1 mL
S	ODIUM CHLORID	(UNII: 451W47IQ8X)		0.009 g ii	n 1 mL
S	ODIUM HYDROXII	DE (UNII: 55X04QC32I)			
P #	ackaging Item Code	Package Description	Marketing Date		Marketing End Date
1	NDC:0268-8069- 50	53 mL in 1 VIAL; Type 0: Not a Combination Product	Dute		Dute
M	larketing l	nformation			
Μ	larketing l Marketing Category	nformation Application Number or Monograph Citation	Marketir Dat		Marketing End Date

FAPP MIXTURE

aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus, gibberella zeae, penicillium chrysogenum var. chrysogenum, phoma exigua var. exigua injection, solution

Product Information					
Product Type	NON-STANDARDIZED ALLERGENIC	lten	n Code (Source)	NDC	:0268-8025
Route of Administration	SUBCUTANEOUS				
Active Ingredient/Active	Majaty				
	•				
Ingre	dient Name		Basis of Streng	jth	Strength
GIBBERELLA ZEAE (UNII: T9GHE8 UNII:T9GHE8H4RX)	H4RX) (GIBBERELLA ZEAE -		GIBBERELLA ZEAE		20000 [PNU] in 1 mL
ASPERGILLUS NIGER VAR. NIGE VAR. NIGER - UNII:9IOA40ANG6)	R (UNII: 9IOA40ANG6) (ASPERGILLUS NIC	GER	ASPERGILLUS NIGER	var.	20000 [PNU] in 1 mL
ASPERGILLUS REPENS (UNII: SQUUNII: SQUU	39E6LOME) (ASPERGILLUS REPENS -		ASPERGILLUS REPENS	5	20000 [PNU] in 1 mL
ASPERGILLUS FLAVUS VAR. OR FLAVUS VAR. ORYZAE - UNII:Q6Z8	ZAE (UNII: Q6Z8UK5R3G) (ASPERGILLU JK5R3G)	IS	ASPERGILLUS FLAVUS VAR. ORYZAE		20000 [PNU] in 1 mL
ASPERGILLUS TERREUS (UNII: QUUNII:QBN8K7055X)	3N8K7055X) (ASPERGILLUS TERREUS -		ASPERGILLUS TERREU	JS	20000 [PNU] in 1 mL
PENICILLIUM CHRYSOGENUM V	AR. CHRYSOGENUM (UNII: 3Y1PE1GC	IG)	PENICILLIUM CHBYSOGENUM VAB		20000 [PNU]

in 1 mL

PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG) CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)

Inactive Ingree	dients		
	Ingredient Name		Strength
SODIUM CHLORIDE	(UNII: 451W47IQ8X)	0.009 g	in 1 mL
SODIUM BICARBON	NATE (UNII: 8MDF5V39QO)	0.0027	g in 1 mL
PHENOL (UNII: 339N	ICG44TV)	0.004 n	nL in 1 mL
HYDROCHLORIC AG	CID (UNII: QTT17582CB)		
SODIUM HYDROXIC	DE (UNII: 55X04QC32I)		
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
Marketing I	nformation		
Marketing Category	Application Number or Monograph Citation	Marketing Star Date	t Marketing End Date
BLA	BLA103753	01/01/1965	05/24/2023

MIXED ASPERGILLUS

aspergillus flavus var. oryzae, aspergillus niger var. niger, aspergillus repens, aspergillus terreus injection, solution

Product Information				
Product Type	NON-STANDARDIZED ALLERGENIC	ltem	Code (Source)	NDC:0268-8034
Route of Administration	SUBCUTANEOUS			
Active Ingradiant/Active	Majaty			
Active Ingredient/Active	Molety			
Ingre	edient Name		Basis of Strengt	h Strength
ASPERGILLUS NIGER VAR. NIGER VAR. NIGER - UNII:9IOA40ANG6)	R (UNII: 9IOA40ANG6) (ASPERGILLUS NIG	GER	ASPERGILLUS NIGER VAR. NIGER	20000 [PNU] in 1 mL
ASPERGILLUS REPENS (UNII: SQ8 UNII:SQ89E6LOME)	39E6LOME) (ASPERGILLUS REPENS -		ASPERGILLUS REPENS	20000 [PNU] in 1 mL
ASPERGILLUS FLAVUS VAR. ORY FLAVUS VAR. ORYZAE - UNII:Q6Z8U	ZAE (UNII: Q6Z8UK5R3G) (ASPERGILLU: JK5R3G)	S	ASPERGILLUS FLAVUS VAR. ORYZAE	20000 [PNU in 1 mL
	3N8K7055X) (ASPERGILLUS TERREUS -		ASPERGILLUS TERREU	20000 [PNU]

		Ingredient Name		Strength
SC	DIUM CHLORID	E (UNII: 451W47IQ8X)	0.009 g i	in 1 mL
sc	DIUM BICARBO	NATE (UNII: 8MDF5V39QO)	0.0027 g	in 1 mL
PH	IENOL (UNII: 3391	NCG44TV)	0.004 mL	in 1 mL
HΥ	DROCHLORIC A	CID (UNII: QTT17582CB)		
sc	DIUM HYDROXI	DE (UNII: 55X04QC32I)		
Pa	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8034- 10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
_		53 mL in 1 VIAL; Type 0: Not a Combination		
2	50	Product		
2	50	Product		
2	50	Product		
		Information		
			Marketing Start Date	Marketing End Date

Labeler - ALK-Abello, Inc. (809998847)

Revised: 5/2023

ALK-Abello, Inc.