5 GRASS MIX- phleum pratense pollen, dactylis glomerata pollen, poa pratensis pollen, agrostis gigantea pollen, anthoxanthum odoratum pollen injection, solution
3 GRASS MIX- bromus inermis pollen, cynodon dactylon, cynodon dactylon injection, solution
4 WEED MIX- amaranthus retroflexus pollen, chenopodium album pollen, plantago lanceolata pollen, xanthium strumarium pollen injection, solution
5 GRASS MIX- agrostis gigantea pollen, anthoxanthum odoratum, dactylis glomerata, phleum pratense, poa pratensis injection, solution
6 GRASS MIX- agrostis gigantea pollen, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis injection, solution
7 GRASS MIX- agrostis gigantea pollen, anthoxanthum odoratum, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis injection, solution
8 SOUTHERN GRASS MIX- agrostis gigantea pollen, cynodon dactylon, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis, sorghum halepense pollen injection, solution
9 SOUTHERN GRASS MIX- agrostis gigantea pollen, anthoxanthum odoratum, cynodon dactylon, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis, sorghum halepense pollen injection, solution
9 TREE MIX- acer saccharum pollen, alnus rhombifolia pollen, betula lenta pollen, carya ovata pollen, fraxinus americana pollen, platanus occidentalis pollen, populus alba pollen, quercus alba pollen, ulmus americana pollen injection, solution
MIXED RAGWEED- ambrosia artemisiifolia, ambrosia trifida pollen injection, solution
WESTERN WEED MIX- ambrosia acanthicarpa pollen, ambrosia psilostachya pollen, artemisia tridentata pollen, bassia scoparia pollen, salsola kali pollen injection, solution
ALK-Abello, Inc.

Center- Al product mixtures

DIRECTIONS FOR USE OF CENTER - AL® THERAPEUTIC
ALLERGENIC EXTRACTS ALUM PRECIPITATED
OF
POLLENS, MOLDS,
INHALANTS AND **EPIDERMALS**
DOSAGE BASED ON
PROTEIN NITROGEN CONTENT

WARNING

This allergenic extract is intended for use by physicians who are experienced in the administration of allergenic extracts for immunotherapy and the emergency care of anaphylaxis, or for use under the guidance of an allergy specialist. These allergenic extracts are not directly interchangeable with allergenic extracts of the same labeled potency from different manufacturers. The patient must be re-evaluated with the newly selected extract. Patients being switched from other types of extracts such as aqueous extracts, glycerinated extracts, or alum precipitated extracts from other suppliers to this allergenic extract should be started as though they were coming under treatment for the first time. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician's office if reaction symptoms occur. **As with all allergenic extracts, severe systemic reactions may occur. In certain individuals, these life-threatening reactions may be fatal.** 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.

Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and/or death. Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk to a fatal outcome from a systemic allergic reaction. If treated, these high risk patients should be started at lower (more conservative) doses and be progressed more slowly to a maintenance dose. Usually this is a lower dose than for those patients without these predispositions. (See **DOSAGE AND ADMINISTRATION**)

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

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 the warnings, precautions and adverse reaction sections below.

Abelló

Port Washington, NY 11050

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DESCRIPTION

Center-Al® (Allergenic extracts, Alum Precipitated) is prepared from aqueous allergenic extracts by the formation of an aluminum hydroxide precipitated complex. It is supplied

as a sterile suspension in multiple dose vials for subcutaneous injection. 0.4% Phenol is added as a preservative.

This product is compounded and diluted on a PNU basis. Extracts containing Short Ragweed Pollen also bear a labeled potency declaration in terms of Antigen E content.

CLINICAL PHARMACOLOGY

Numerous studies have confirmed Antigen E (AgE) as the major antigen associated with Short Ragweed pollinosis. In a well-controlled study, purified Antigen E was significantly superior to placebo in amelioration of symptoms associated with Short Ragweed pollinosis.[1] Therefore, it is essential that the physician be aware of AgE content of allergenic extracts 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 a 0.1 unit is a maximum tolerated dose. Most moderately sensitive patients may tolerate a dosage ten to fifty times greater. For exquisitely sensitive patients who cannot tolerate an immunizing dose of this preparation, the physician should consider immunotherapy with alternatives to conventional aqueous allergenic extract.

Alum precipitated bacterial and viral vaccines and alum precipitated toxoids have been effectively and routinely used in immunization injections for many years. The explanation usually given for the effect of such preparations is that the physical chemical absorption of an antigen onto an alum complex results in a slower release of the antigen with a consequent prolongation of the antigenic stimulus.

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. Although the exact relationships between allergen, skin-sensitizing antibody (IgE) and the blocking antibody (IgG) have not been precisely established, clinically confirmed immunological studies have demonstrated the safety of **Center-Al** extracts and effectiveness in terms of symptom reduction and IgG response consistent with dose administered.[3]

In a controlled study with **Center-Al** Ragweed given pre-seasonally, patients were selected and matched by histamine release to Antigen E and assigned to treatment groups: Aqueous, **Center-Al**, and Placebo.[3] All patients were highly sensitive to Ragweed Antigen E, reacting to <0.001 mcg Antigen E/mL as determined by intradermal skin testing. These patients received a pre-seasonal course of immunotherapy and achieved a mean cumulative dose of 52 units of Antigen E (27,365 PNU) in 13 to 19 injections. Starting doses in these patients were 10 PNU or approximately 0.02 units of AgE. This dosage was found to be significantly superior to Placebo as measured by symptom scores during the ragweed pollen season.

Although maximum tolerated doses for **Center-Al** expressed in AgE content have not specifically been studied, one investigator reported maximum tolerated doses with **Center-Al** ragweed at 2,000-5,000 PNU (4-10 units of Antigen E) with previously untreated patients.[9] At least three investigators using mixed (tall and short) ragweed extracts demonstrated a maximum tolerated peak dose of 2,000 to 10,000 PNU in 10-

13 injections in moderately sensitive patients.[6,10-12] This was achieved by roughly doubling the dose in each successive injection at low dosages (<1,000 PNU) and if well tolerated, increasing the dosage approximately 50% until maximum tolerated dose for each patient was achieved.

Reaction rates for these patients were significantly lower than patients treated with aqueous extracts with the same or more conservative dosage regimen.[3,7,8,11]

INDICATIONS AND USAGE

Hyposensitization (injection) therapy is a treatment for patients exhibiting allergic reactions to seasonal pollens, dust mites, molds, animal danders, and various other inhalants, in situations where the offending allergen cannot be avoided.

Prior to the initiation of therapy, 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 be easily avoided.

CONTRAINDICATIONS

A patient should not be immunized against a substance which the patient has not demonstrated symptoms and/or tissue-fixed IgE antibodies as demonstrated by skin testing. Immunotherapy should not be attempted in patients with active asthma, severe respiratory obstruction, or cardiovascular disease.

There is some evidence, although inconclusive, that routine immunizations may exacerbate autoimmune diseases. Hyposensitization should be given cautiously to patients with this predisposition. The physician must weigh risk to benefit in these rare cases.

Patients with Alzheimer's disease, Down's syndrome and renal insufficiency are theoretically at risk from aluminum intake, including alum precipitated allergenic extracts.

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 1.0 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 is then gradually released. Patients under treatment with beta-blockers may be refractory to the usual dose of epinephrine.

PRECAUTIONS

Information For 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.

General:

1. **Center-Al** Allergenic Extracts, Alum Precipitated, are not to be used for intradermal testing.
2. Store at temperatures 2° and 8°C at all times, even during use.
3. DO NOT FREEZE. Freezing may cause agglomeration.
4. Shake vial thoroughly to disperse suspension prior to removal of the dose to be administered.
5. A separate sterile syringe and needle should be used for each individual patient, to prevent transmission of homologous serum hepatitis and other infectious agents from one person to another.
6. Injections are to be administered subcutaneously with the usual sterile precautions, preferably in the upper outer aspects of the arm, using a sterile tuberculin- type syringe and 25 or 26 gauge needle, 1⁄2 to 1⁄4 in length.
7. Avoid injecting intravenously. Pull back gently on syringe plunger and note if blood enters the syringe. If blood should enter the syringe, withdraw the needle and reinsert at another site, repeating the same precaution.
8. 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, usually reducing the dosage of the first injection of the new vial 50-75% of the previous well tolerated dose of the older vial.
9. Subcutaneous nodules may develop at injection sites. The incidence of nodules increases with higher dosage of individual products and with extemporaneous mixtures at lower dosage. No single dose should provide more than 5,000 PNU whether as single allergen or mixture, nor should it exceed 0.5 mL in volume. If nodules occur, the highest single dose administered should be limited to a maximum of 0.2 mL (2,000 PNU).

DRUG INTERACTIONS:

Center-Al Allergenic Extracts, Alum Precipitated, are not to be mixed with any non-alum containing allergen(s) or with other types of alum precipitated products. Such mixing may free the alum-absorbed allergens.

Center-Al Allergenic Extracts, Alum Precipitated, should be diluted only with Sterile Diluent for Allergenic Extracts (Phenol-Saline) containing 0.9% Sodium Chloride, 0.4% Phenol. Use of other types of diluents may result in re-solution of some of the alum-complexed allergen thereby resulting in release of free aqueous extracts.

Patients receiving beta-blockers may not be responsive to epinephrine or an inhaled bronchodilator.

PREGNANCY - CATEGORY C:

Animal reproduction studies have not been conducted with **Center-Al** (Allergenic Extracts, Alum Precipitated). It is also not known whether **Center-Al** 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 the 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 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.

ADVERSE 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: It should be noted that anaphylaxis and deaths following the injection of mite and other extracts, including pollen extracts, have been reported by The British Committee on Safety in Medicine.[13] Fatalities from immunotherapy in the United States since 1945 have been extensively reviewed by Lockey, R.F., et al.[14] and also more recently by Reid, M.J., et al.[15] 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.

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 20-30 minutes after any injection.

Volume expanders and vasopressor agents may be required to reverse hypotension. Inhalational bronchodilator and parenteral aminophylline may be required to reverse bronchospasm. Severe airway obstruction, unresponsive to bronchodilator, may require tracheal intubation.

In the event of a marked systemic reaction, application of a tourniquet above the injection site and administration of 0.2 mL to 1.0 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 is then gradually released.

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.

Adverse Events should be reported via MedWatch (1-800-FDA-1088), Adverse Event Reporting, Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

DOSAGE AND ADMINISTRATION

The starting dose for immunotherapy is related directly to a patient's sensitivity as determined by carefully executed percutaneous (prick/puncture) and intracutaneous (intradermal) skin testing with non-alum adsorbed allergenic extract. A general rule is to begin at 1/10 of the intradermal dose that produces sum of erythema of 50 mm (approximately a 2+ positive skin test reaction). Patient's response to skin testing is graded on the basis of the size of the erythema and wheal. Refer to the diagnostic allergenic extract package enclosure for specific information.

TRANSFER OF PATIENTS FROM OTHER AQUEOUS EXTRACTS TO **CENTER-AL** EXTRACTS

Patients may be transferred from other aqueous allergens to **Center-Al** Alum Precipitated Extracts during treatment. To avoid untoward reactions, it may be necessary to initiate treatment as though the patient were previously untreated. In transferring from standardized extracts, the more rapid rate of decline in activity of aqueous extract relative to alum precipitated extract must be considered in cautiously transferring patients to alum precipitated extract.

Caution should be observed since the **Center-Al** preparation may be more potent than the aqueous product.

TRANSFER OF PATIENTS FROM OTHER ALUM-COMPLEXED EXTRACTS TO **CENTER-AL** EXTRACTS

Patients may be transferred from other alum-complexed allergenic extracts to **Center-Al** Alum Precipitated extracts. In order to avoid untoward reactions, it is recommended that previous therapy be disregarded and therapy with **Center-Al** be initiated as though the patient were previously untreated. The first dose of **Center-Al** should be related to the patient's sensitivity, determined by history and confirmed by skin testing. CAUTION: **Center-Al** Alum Precipitated extracts should not be mixed with other alum precipitated

or aqueous extracts.

PRE-SEASONAL AND PERENNIAL METHOD OF TREATMENT

The use of **Center-Al** Allergenic extract, Alum Precipitated, in the treatment of patients by the pre-seasonal method should be started 10 to 12 weeks prior to the usual onset of symptoms. Therapy should be initiated early enough to permit a graduated series of doses at weekly intervals. It is recommended that the larger doses be spaced 2 to 3 weeks apart and that the top dose be reached prior to the season.

Increased tolerance acquired through hyposensitization can vary from a few to several months. To assure prolongation of this acquired tolerance, perennial or year-round treatment is recommended. Some physicians continue therapy into or through the season by repeating a reduced MAINTENANCE dose at 4 to 6 week intervals.

SUGGESTED DOSAGE SCHEDULE

A treatment schedule is related directly to the patient's degree of sensitivity, determined initially by clinical history and skin testing, and continuously by response to therapeutic doses. Thus, an individual treatment schedule for each patient must be established during the course of therapy. Maximum protection can be obtained with a dosage kept constantly below the patient's limit of tolerance. Every precaution should be taken to avoid a systemic or generalized reaction which in addition to being dangerous, may depress rather than increase the patient's tolerance.

FOR ALL PREPARATIONS (EXCEPT SHORT RAGWEED AND MIXED SHORT AND TALL RAGWEED)

Labeled Antigen E content of extracts containing Short Ragweed at a weight/volume concentration more dilute than 1:10 may have been obtained by calculation from the Antigen E assay value of a more concentrated extract that was analyzed, officially released by the Office of Biologics, and subsequently diluted.

Below is listed a suggested dosage schedule for Pre-Seasonal Treatment. A column has been left blank for AgE dosage of short ragweed containing extracts.

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 formula:

$$\frac{\text{Labeled AgE}}{\text{Labeled PNU/mL}} \times \text{dose in PNU} = \text{dose in AgE}$$

Note: Suggested dosage schedules which follow have not been subjected to adequate and well controlled trials to establish their safety and efficacy.

Dose No.	Vial Strength	Volume Injected	PNU Per Dose	AgE Dose
1	100 PNU/mL	0.1 mL	10	
2	100 PNU/mL	0.2 mL	20	
3	100 PNU/mL	0.5 mL	50	
4	1,000 PNU/mL	0.1 mL	100	

5	1,000 PNU/mL	0.25 mL	250	
6	1,000 PNU/mL	0.5 mL	500	
7	10,000 PNU/mL	0.1 mL	1,000	
8	10,000 PNU/mL	0.2 mL	2,000	
9	10,000 PNU/mL	0.3 mL	3,000	
10	10,000 PNU/mL	0.4 mL	4,000	
11	10,000 PNU/mL	0.5 mL	5,000	

MAINTENANCE DOSE:		
10,000 PNU/mL	**0.5 mL**	**5,000**

NO SINGLE DOSE SHOULD EXCEED 5,000 PNU. For continuing therapy with extracts containing Short Ragweed, see following section on Dosage Adjustments.

SHORT RAGWEED EQUAL PARTS MIXES OF SHORT AND TALL RAGWEED (DOSAGE BASED ON ANTIGEN CONTENT)

Suggested dosage schedule for Short Ragweed and Equal Part Mixture of Short and Tall Ragweed:

Dose No	**AgE Units/mL**	**Volume Injected**	**AgE Per Dose**
1	0.4	0.1	0.04
2	0.4	0.2	0.08
3	0.4	0.5	0.2
4	4	0.1	0.4
5	4	0.25	1.0
6	4	0.5	2.0
7	40	0.1	4.0
8	40	0.2	8.0
9	40	0.3	12
10	40	0.4	16
11	40	0.5	20

MAINTENANCE DOSE:		
40	0.5	20
80	0.25	20

NO SINGLE DOSE SHOULD EXCEED 20 UNITS

DOSAGE ADJUSTMENTS
(FOR PRODUCTS CONTAINING SHORT RAGWEED)

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 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 50% glycinerated or Alum Precipitated extracts. Antigen E is most stable in freeze-dried extracts. These differences are reflected in the expiration date declared on the vial label. 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.

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

HOW SUPPLIED

Therapeutic **Center-Al** Allergenic Extracts, Alum Precipitated, are supplied in 10 mL and 30 mL vials, in concentrations of 10,000 PNU/mL and 20,000 PNU/mL. Prescription treatment sets for individual patients are also available. **Center-Al** must be stored continuously at 2° to 8°C. DO NOT FREEZE. Diluent: Sterile Diluent for allergenic extracts (Phenol-Saline) is provided in vials of 4.5 mL, 9.0 mL, and 30 mL.

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 **42:**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. **61:384, 1978.**
3. Norman, P.S. and Lichtenstein, L.M.: Comparisons of alum precipitated and unprecipitated aqueous ragweed pollen extracts in the treatment of hayfever. J. Allergy Clin. Immunol. **61:**384, 1978.
4. Ransom, J.H.: Clinical and laboratory evaluation of alum precipitated ragweed extract. Ann. Allergy **28:**22, 1970.
5. Ransom, J.H.: Frequency of reactions to alum precipitated ragweed extract. Ann. Allergy **29:**635, 1971.
6. Lazar, H. and Leoffler, J.A.: Evaluation of an alum precipitated mixed ragweed antigen: a three-year study. Ann. Allergy **28:**214, 1970.
7. Norman, P.S., Winkenwerder, W.L., and Lichtenstein, L.M.: Trials of alum precipitated pollen extracts in the treatment of hayfever. J. Allergy Clin. Immunol. **50:**31, 1972.
8. Nelson, H.S.: Long-term immunotherapy with aqueous and alum precipitated grass extracts. Ann. Allergy **45:**333, 1980.

9. Norman,. P.S.: The role of In-Vitro assays in the evaluation of immunotherapy. Recent Advances in Immunotherapy. Port Washington, NY 1973.
10. Lazar, H.: Clinical presentation covering 6 years of observation. Recent Advances in Immunotherapy. Port Washington, NY 1973.
11. Haynes, J.T.: A clinical study of 23 ragweed sensitive patients. Recent Advances in Immunotherapy. Port Washington, NY 1973.
12. Ransom, J.H.: Ragweed patient study. Recent Advances in Immunotherapy. Port Washington, NY 1973.
13. Committee on the Safety of Medicines. CSM update: desensitizing vaccines. Brit. Med. J. 1986; 293:948.
14. Lockey, R.F. et al.: Fatalities from immunotherapy (IT) and skin testing (ST). J. Allergy Clin. Immunol. 1987; 79:660.
15. Reid, M.J. et al.: Survey of fatalities from skin testing and immunotherapy. 1985-1989. J. Allergy Clin. Immunol. 1993; 92:6.

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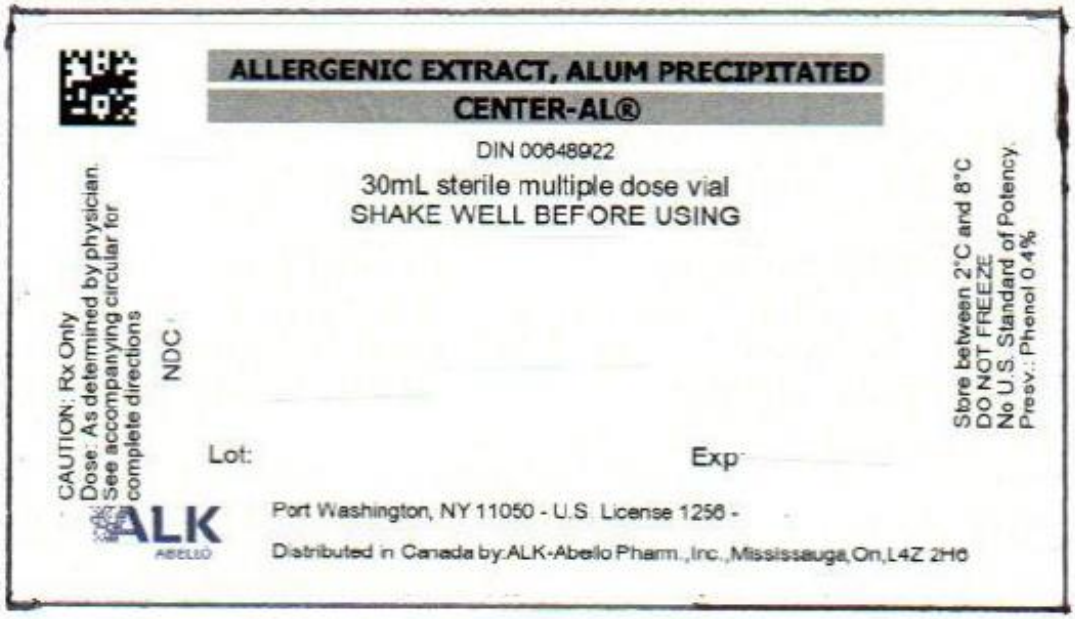
168H

Distributed in Canada by:
ALK-Abello Pharmaceuticals, Inc.
#35-151 Brunel Road Mississauga, Ontario
Canada L4Z 2H6

PRINCIPAL DISPLAY PANEL

Allergenic Extract, Alum Precipitated
Center-AL
DIN 00648922
30 mL Sterile Multiple Dose Vial



5 GRASS MIX

phleum pratense pollen, dactylis glomerata pollen, poa pratensis pollen, agrostis gigantea pollen, anthoxanthum odoratum pollen injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8005
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	1000 [PNU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	1000 [PNU] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	1000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	1000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	1000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-8005-05	5.5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/25/2023

5 GRASS MIX

phleum pratense pollen, dactylis glomerata pollen, poa pratensis pollen, agrostis gigantea pollen, anthoxanthum odoratum pollen injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8006
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	5000 [PNU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	5000 [PNU] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	5000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	5000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	5000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-8006-05	5.5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/25/2023

5 GRASS MIX

phleum pratense pollen, dactylis glomerata pollen, poa pratensis pollen, agrostis gigantea pollen, anthoxanthum odoratum pollen injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8007
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	10000 [PNU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	10000 [PNU] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	10000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	10000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	10000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-8007-05	5.5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/25/2023

5 GRASS MIX

phleum pratense pollen, dactylis glomerata pollen, poa pratensis pollen, agrostis gigantea pollen, anthoxanthum odoratum pollen injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8010
Route of Administration	SUBCUTANEOUS		

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

PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	100 [PNU] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	100 [PNU] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	100 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	100 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	100 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8010-05	5.5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

3 GRASS MIX

bromus inermis pollen, cynodon dactylon, cynodon dactylon injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8001
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON WHOLE (UNII: 2Q8MR21NHK) (CYNODON DACTYLON WHOLE - UNII:2Q8MR21NHK)	CYNODON DACTYLON WHOLE	20000 [PNU] in 1 mL
BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6)	BROMUS INERMIS POLLEN	20000 [PNU] in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	20000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-8001-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/25/2023

4 WEED MIX

amaranthus retroflexus pollen, chenopodium album pollen, plantago lanceolata pollen, xanthium strumarium pollen injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8004
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
XANTHIUM STRUMARIUM POLLEN (UNII: 2QOF601J1M) (XANTHIUM STRUMARIUM POLLEN - UNII:2QOF601J1M)	XANTHIUM STRUMARIUM POLLEN	10000 [PNU] in 1 mL
PLANTAGO LANCEOLATA POLLEN (UNII: DO87T1U2CI) (PLANTAGO LANCEOLATA POLLEN - UNII:DO87T1U2CI)	PLANTAGO LANCEOLATA POLLEN	10000 [PNU] in 1 mL
CHENOPODIUM ALBUM POLLEN (UNII: 098LKX5NCN) (CHENOPODIUM ALBUM POLLEN - UNII:098LKX5NCN)	CHENOPODIUM ALBUM POLLEN	10000 [PNU] in 1 mL
AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW)	AMARANTHUS RETROFLEXUS POLLEN	10000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL

SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8004-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	

5 GRASS MIX

agrostis gigantea pollen, anthoxanthum odoratum, dactylis glomerata, phleum pratense, poa pratensis injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8008
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	10000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	10000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	10000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	10000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM (UNII: YMW1K70E4Q) (ANTHOXANTHUM ODORATUM - UNII:YMW1K70E4Q)	ANTHOXANTHUM ODORATUM	10000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL

HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8008-10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0268-8008-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	

5 GRASS MIX

agrostis gigantea pollen, anthoxanthum odoratum, dactylis glomerata, phleum pratense, poa pratensis injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8009
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	20000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	20000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	20000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	20000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM (UNII: YMW1K70E4Q) (ANTHOXANTHUM ODORATUM - UNII:YMW1K70E4Q)	ANTHOXANTHUM ODORATUM	20000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8009-10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/25/2023

6 GRASS MIX

agrostis gigantea pollen, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8011
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	10000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	10000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	10000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	10000 [PNU] in 1 mL
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9)	FESTUCA PRATENSIS	10000 [PNU] in 1 mL
LOLIUM PERENNE (UNII: 7C82Y2EF9V) (LOLIUM PERENNE - UNII:7C82Y2EF9V)	LOLIUM PERENNE	10000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8011-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

6 GRASS MIX

agrostis gigantea pollen, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8012
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	20000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	20000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	20000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	20000 [PNU] in 1 mL
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9)	FESTUCA PRATENSIS	20000 [PNU] in 1 mL
LOLIUM PERENNE (UNII: 7C82Y2EF9V) (LOLIUM PERENNE - UNII:7C82Y2EF9V)	LOLIUM PERENNE	20000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8012-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

7 GRASS MIX

agrostis gigantea pollen, anthoxanthum odoratum, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8013
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	10000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	10000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	10000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	10000 [PNU] in 1 mL
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9)	FESTUCA PRATENSIS	10000 [PNU] in 1 mL
LOLIUM PERENNE (UNII: 7C82Y2EF9V) (LOLIUM PERENNE - UNII:7C82Y2EF9V)	LOLIUM PERENNE	10000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM (UNII: YMW1K70E4Q) (ANTHOXANTHUM ODORATUM - UNII:YMW1K70E4Q)	ANTHOXANTHUM ODORATUM	10000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8013-10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0268-8013-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

7 GRASS MIX

agrostis gigantea pollen, anthoxanthum odoratum, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8014
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	20000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	20000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	20000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	20000 [PNU] in 1 mL
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9)	FESTUCA PRATENSIS	20000 [PNU] in 1 mL
LOLIUM PERENNE (UNII: 7C82Y2EF9V) (LOLIUM PERENNE - UNII:7C82Y2EF9V)	LOLIUM PERENNE	20000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM (UNII: YMW1K70E4Q) (ANTHOXANTHUM ODORATUM - UNII:YMW1K70E4Q)	ANTHOXANTHUM ODORATUM	20000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8014-10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0268-8014-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

8 SOUTHERN GRASS MIX

agrostis gigantea pollen, cynodon dactylon, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis, sorghum halepense pollen injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8015
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON WHOLE (UNII: 2Q8MR21NHK) (CYNODON DACTYLON WHOLE - UNII:2Q8MR21NHK)	CYNODON DACTYLON WHOLE	10000 [PNU] in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	10000 [PNU] in 1 mL
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	10000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	10000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	10000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	10000 [PNU] in 1 mL
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9)	FESTUCA PRATENSIS	10000 [PNU] in 1 mL
LOLIUM PERENNE (UNII: 7C82Y2EF9V) (LOLIUM PERENNE - UNII:7C82Y2EF9V)	LOLIUM PERENNE	10000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL

SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8015-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

8 SOUTHERN GRASS MIX

agrostis gigantea pollen, cynodon dactylon, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis, sorghum halepense pollen injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8016
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON WHOLE (UNII: 2Q8MR21NHK) (CYNODON DACTYLON WHOLE - UNII:2Q8MR21NHK)	CYNODON DACTYLON WHOLE	20000 [PNU] in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	20000 [PNU] in 1 mL
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	20000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	20000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	20000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	20000 [PNU] in 1 mL
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9)	FESTUCA PRATENSIS	20000 [PNU] in 1 mL
LOLIUM PERENNE (UNII: 7C82Y2EF9V) (LOLIUM PERENNE - UNII:7C82Y2EF9V)	LOLIUM PERENNE	20000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL

PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8016-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

9 SOUTHERN GRASS MIX

agrostis gigantea pollen, anthoxanthum odoratum, cynodon dactylon, dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis, sorghum halepense pollen injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8017
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON WHOLE (UNII: 2Q8MR21NHK) (CYNODON DACTYLON WHOLE - UNII:2Q8MR21NHK)	CYNODON DACTYLON WHOLE	10000 [PNU] in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	10000 [PNU] in 1 mL
PHLEUM PRATENSE (UNII: 0P46LFE4VC) (PHLEUM PRATENSE - UNII:0P46LFE4VC)	PHLEUM PRATENSE	10000 [PNU] in 1 mL
DACTYLIS GLOMERATA (UNII: 9182Z61D36) (DACTYLIS GLOMERATA - UNII:9182Z61D36)	DACTYLIS GLOMERATA	10000 [PNU] in 1 mL
POA PRATENSIS (UNII: ZO990O27NP) (POA PRATENSIS - UNII:ZO990O27NP)	POA PRATENSIS	10000 [PNU] in 1 mL
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	10000 [PNU] in 1 mL
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9)	FESTUCA PRATENSIS	10000 [PNU] in 1 mL
LOLIUM PERENNE (UNII: 7C82Y2EF9V) (LOLIUM PERENNE - UNII:7C82Y2EF9V)	LOLIUM PERENNE	10000 [PNU] in 1 mL
ANTHOXANTHUM ODORATUM (UNII: YMW1K70E4Q) (ANTHOXANTHUM ODORATUM - UNII:YMW1K70E4Q)	ANTHOXANTHUM ODORATUM	10000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8017-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

9 TREE MIX

acer saccharum pollen, alnus rhombifolia pollen, betula lenta pollen, 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	**Item Code (Source)**	NDC:0268-8023
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	10000 [PNU] in 1 mL
FRAXINUS AMERICANA POLLEN (UNII: G684LX721Q) (FRAXINUS AMERICANA POLLEN - UNII:G684LX721Q)	FRAXINUS AMERICANA POLLEN	10000 [PNU] in 1 mL
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)	ULMUS AMERICANA POLLEN	10000 [PNU] in 1 mL
BETULA LENTA POLLEN (UNII: JQ5HI5004M) (BETULA LENTA POLLEN - UNII:JQ5HI5004M)	BETULA LENTA POLLEN	10000 [PNU] in 1 mL
ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861)	ACER SACCHARUM POLLEN	10000 [PNU] in 1 mL
CARYA OVATA POLLEN (UNII: 54UN9R2798) (CARYA OVATA POLLEN - UNII:54UN9R2798)	CARYA OVATA POLLEN	10000 [PNU] in 1 mL
QUERCUS ALBA POLLEN (UNII: Z4Y9ZSV4KK) (QUERCUS ALBA POLLEN - UNII:Z4Y9ZSV4KK)	QUERCUS ALBA POLLEN	10000 [PNU] in 1 mL
POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII:VU8C8SB23P)	POPULUS ALBA POLLEN	10000 [PNU] in 1 mL

PLATANUS OCCIDENTALIS POLLEN (UNII: E03U1K03LK) (PLATANUS OCCIDENTALIS POLLEN - UNII:E03U1K03LK)	PLATANUS OCCIDENTALIS POLLEN	10000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.005 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8023-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0268-8023-10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	

MIXED RAGWEED

ambrosia artemisiifolia, ambrosia trifida pollen injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8057
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMBROSIA ARTEMISIIFOLIA (UNII: 9W34L2CQ9A) (AMBROSIA ARTEMISIIFOLIA - UNII:9W34L2CQ9A)	AMBROSIA ARTEMISIIFOLIA	10000 [PNU] in 1 mL
AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX)	AMBROSIA TRIFIDA POLLEN	10000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL

SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8057-10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0268-8057-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	

MIXED RAGWEED

ambrosia artemisiifolia, ambrosia trifida pollen injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8058
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMBROSIA ARTEMISIIFOLIA (UNII: 9W34L2CQ9A) (AMBROSIA ARTEMISIIFOLIA - UNII:9W34L2CQ9A)	AMBROSIA ARTEMISIIFOLIA	20000 [PNU] in 1 mL
AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX)	AMBROSIA TRIFIDA POLLEN	20000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.004 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8058-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	

WESTERN WEED MIX

ambrosia acanthicarpa pollen, ambrosia psilostachya pollen, artemisia tridentata pollen, bassia scoparia pollen, salsola kali pollen injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-8079
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5) (BASSIA SCOPARIA POLLEN - UNII:07A108ZKW5)	BASSIA SCOPARIA POLLEN	10000 [PNU] in 1 mL
ARTEMISIA TRIDENTATA POLLEN (UNII: YI19RB8YFD) (ARTEMISIA TRIDENTATA POLLEN - UNII:YI19RB8YFD)	ARTEMISIA TRIDENTATA POLLEN	10000 [PNU] in 1 mL
AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L)	AMBROSIA PSILOSTACHYA POLLEN	10000 [PNU] in 1 mL
AMBROSIA ACANTHICARPA POLLEN (UNII: U2AI3H2J5Y) (AMBROSIA ACANTHICARPA POLLEN - UNII:U2AI3H2J5Y)	AMBROSIA ACANTHICARPA POLLEN	10000 [PNU] in 1 mL
SALSOLA KALI POLLEN (UNII: 2MH135KC6G) (SALSOLA KALI POLLEN - UNII:2MH135KC6G)	SALSOLA KALI POLLEN	10000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01 g in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-8079-30	32 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103753	01/15/1975	05/24/2023

Labeler - ALK-Abello, Inc. (809998847)

Revised: 5/2023 ALK-Abello, Inc.