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, INHALANT**S 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 lifethreatening 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 overdosage 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 alumcomplexed 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-AI** (Allergenic Extracts, Alum Precipitated). It is also not known whether **Center-AI** 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-AI** 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-AI** Alum Precipitated extracts. In order to avoid untoward reactions, it is recommended that previous therapy be disregarded and therapy with **Center-AI** be initiated as though the patient were previously untreated. The first dose of **Center-AI** should be related to the patient's sensitivity, determined by history and confirmed by skin testing. CAUTION: **Center-AI** 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:

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

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.

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PRINCIPAL DISPLAY PANEL

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

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5 GRASS MIX

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

Product Infor	mation					
Product Type		NON-STANDARDIZED ALLERGENIC	ltem	Code (Source)	ND	C:0268-8005
Route of Admini	stration	SUBCUTANEOUS				
Active Ingredi	ent/Active	Moiety				
	Ingre	dient Name		Basis of Strer	ngth	Strength
PHLEUM PRATENS POLLEN - UNII:65M8	E POLLEN (UN	II: 65M88RW2EG) (PHLEUM PRATEN	ISE	PHLEUM PRATENSE POLLEN	-	1000 [PNU] in 1 mL
DACTYLIS GLOME POLLEN - UNII:83N7		(UNII: 83N78IDA7P) (DACTYLIS GLO	OMERATA	DACTYLIS GLOMER POLLEN	ATA	1000 [PNU] in 1 mL
POA PRATENSIS P UNII:SCB8J7LS3T)	OLLEN (UNII: S	CB8J7LS3T) (POA PRATENSIS POLL	EN -	POA PRATENSIS PO	OLLEN	1000 [PNU] in 1 mL
POLLEN - UNII:HU8V	6E7HOA)	NII: HU8V6E7HOA) (AGROSTIS GIG		AGROSTIS GIGANT POLLEN	ΈA	1000 [PNU] in 1 mL
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5 GRASS MIX

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

PHEEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)PHLEUM PRATENSE POLLENS000 [PNU in 1 mLDACTYLIS GLOMERATA POLLEN (UNII: 83N78iDA7P)(DACTYLIS GLOMERATA POLLEN - UNII:83N78iDA7P)DACTYLIS GLOMERATA POLLENDACTYLIS GLOMERATA POLLEN5000 [PNU in 1 mLPOA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS FOLLEN - UNII:SCB8J7LS3T)POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS GIGANTEA POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN UNII: 2KIK19R45Y)S000 [PNU in 1 mLInactive IngredientsIngredient NameStrengthPOTASSIUM ALUMINATE (UNII: TGN4M9CD7R)0.05 g in 1 mLSODIUM HYDROXIDE (UNII: 55X04QC32I)0.01 g in 1 mLPHENOL (UNII: 339NCG44TV)0.004 mL in 1 mLSODIUM CHLORIDE (UNII: 451W47IQ8X)0.009 g in 1 mLHYDROCHLORIC ACID (UNII: QTT17582CB)UNII: 2KIK19R45Y)								
SUBCUTANEOUS Active Ingredient/Active Moiety Mactive Ingredient/Active Moiety PHLEUM PRATENSE POLLEN (UNII: 65M8BRW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M8BRW2EG) Basis of Strength POLLEN - DUNI:65M8BRW2EG) Strengt POLLEN - DUNI:65M8BRW2EG) DACTYLIS GLOMERATA POLLEN (UNII: 65M8BRW2EG) (PALEUM PRATENSIS POLLEN - UNII:65M8BRW2EG) DACTYLIS GLOMERATA POLLEN - UNII:65M8BRW2EG) POLLEN - DACTYLIS GLOMERATA DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLEN - UNII:53X31) POA PRATENSIS POLLEN - UNII:52B37(SIST) POA PRATENSIS POLLEN (UNII: 52B3/7LS31) (POA PRATENSIS POLLEN - UNII:52B37(SIGANTEA POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y) POA PRATENSIS POLLEN - POLLEN - UNII:080627HOA) MATHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y) MATHOXANTHUM ODORATUM POLLEN - UNII:2SKI19R45Y) Strength ODORATUM POLLEN - UNII:2SKI19R45Y) Strength ODORATUM POLLEN - UNII:2SKI19R45Y) Strength ODORATUM POLLEN - UNII:00007A1UM POLLEN - UNII:2SKI19R45Y) 0.01 g in 1 mL ODORATUM POLLEN - UNII:2SKI19R45Y) Strength ODORATUM POLLEN - UNII:2SKI19R45Y) 0.00 g in 1 mL ODORATUM POLLEN - UNII:2SKI19R45Y) 0.00 g in 1 mL ODORATUM POLLEN - UNII:2SKI19R45Y) 0.00 g in 1 mL ODOBATUM POLLEN - UNII:2SKI19R45Y) UNI:2SKI19R45Y) 0.00 g in 1 mL DACTYLISSKI19R45Y) DOODATUM POLLEN - UNII:2SKI19R45Y)	Product Infor	mation						
Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength PHLEUM PRATENSE POLLEN (UNII: 63M88RW2EG) (PHLEUM PRATENSE PHLEUM PRATENSE S000 [PNU in 1 mL DOLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN In 1 mL DOLLEN VINI:65M88RW2EG) DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN In 1 mL DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) POLATINIS POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN In 1 mL DACTYLIS GLOMERATA POLLEN (UNII: 8000 [PNU In 1 mL DACTYLIS GIGANTEA POLLEN (UNII: 8000 [PNU In 1 mL DOLEN - UNII:HU8V627HOA) (AGROSTIS GIGANTEA POLLEN INII: HU8V627HOA) (AGROSTIS GIGANTEA POLLEN INII: HU8V627HOA) (AGROSTIS GIGANTEA DOLEN - UNII:HU8V627HOA) Strength 000 [PNU In 1 mL DODRATUM POLLEN - UNII:EXIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN INII: TO NAM9CD7R) OLIG Ingredient Name Strength POTASSIUM ALUMINATE (UNII: TO NAM9CD7R) 0.00 fPNU INII: MUII: S30N2G44TV) 0.004 mL in 1 mL Strength Strength Strength PACkaging # Item Code Package Description Marketing Start Marketing End Date Date NII: Sincle Pollen UNII: SINCLER POLLEN (UNII: 451W47IQ8X) 0.004 mL in 1 mL DOLCEN (UNII: 451W47IQ8X)	Product Type		NON-STANDARDIZED ALLERGEN	IC Iter	n Code (Source	e) ND	C:0268-8006	
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: SCB8J7LS 3T) DACTYLIS GLOMERATA POLLEN (UNII: SCB8J7LS 3T) POA PRATENSIS POLLEN - POLLEN - UNII:SCB8J7LS 3T) POA PRATENSIS POLLEN - POA PRATENSIS POLLEN (UNII: SCB8J7LS 3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS 3T) POA PRATENSIS POLLEN - POA PRATENSIS POLLEN (UNII: SCB8J7LS 3T) (POA PRATENSIS GIGANTEA AGROSTIS GIGANTEA POLLEN (UNII: HUBV6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HUBV6E7HOA) AGROSTIS GIGANTEA AGROSTIS GIGANTEA POLLEN - UNII:SCB8J7LS 3T) (POA PRATENSIS POLLEN - POLLEN - UNII:HUBV6E7HOA) SOOI (PNU in 1 mL ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) AGROSTIS GIGANTEA POLLEN Strength Inactive Ingredients Ingredient Name Strength 0.00 (PNU in 1 mL SODIUM HYDROXDE (UNII: 55N40QC32I) 0.01 g in 1 mL 0.004 mL in 1 mL SODIUM HYDROXDE (UNII: 451W47IQ8X) 0.009 g in 1 mL 0.009 g in 1 mL PHENOL (UNII: 339NCG44TV) 0.009 g in 1 mL 0.009 g in 1 mL SODIUM CHLORIDE (UNII: 651W47) 0.009 g in 1 mL 0.009 g in 1 mL 1 NDC:02668-8006- 5.5 mL in 1 VIAL; Type	Route of Admin	istration	SUBCUTANEOUS					
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:63M78IDA7P) DACTYLIS GLOMERATA POLLEN 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: BUBV6E7HOA) (AGROSTIS GIGANTEA ARTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) 0.05 g in 1 mL Inactive Ingredients Ingredient Name Strength POTASSIUM ALUMINATE (UNII: TGN4M9CD7R) 0.05 g in 1 mL SODIUM HYDROXDE (UNII: 451W47IQ8X) 0.004 mL in 1 mL SODIUM HYDROXDE (UNII: 451W47IQ8X) 0.009 g in 1 mL HTEM Code Package Description Marketing Start Date Marketing End Date 1 NDC:02668-8006- 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Marketing End Date Date								
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG) PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG) PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG) SO00 (PNU in 1 mL 5000 (PNU POLLEN - UNII:65M8RW2EG) POA PRATENSIS POLLEN (UNII: SCB8)7LS3T) (POA PRATENSIS POLLEN - POA PRATENSIS POLLEN (UNII: SCB8)7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8)7LS3T) POA PRATENSIS POLLEN - POA PRATENSIS GIGANTEA POLLEN (UNII: SCB8)7LS3T) (POA PRATENSIS POLLEN - POA PRATENSIS GIGANTEA POLLEN (UNII: SCB627HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) So00 (PNU in 1 mL 5000 (PNU POLLEN - UNII:HU8V6E7HOA) ARROSTIS GIGANTEA POLLEN (UNII: SCB497K) AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) Strength POLLEN - DODRATUM POLLEN - UNII:ZKIK19R45Y) Inactive Ingredients Strength POTASSIUM ALUMINATE (UNII: SCM40C32I) 0.05 g in 1 mL 9000 m HYDROXIDE (UNII: 55X04QC32I) 0.00 g in 1 mL 9000 m HYDROXIDE (UNII: 55X04QC32I) 0.00 g in 1 mL 9000 m HYDROXIDE (UNII: 451W47IQ8X) 0.009 g in 1 mL 9000 m HYDROCHLORIC ACID (UNII: CTT17582CB) Packaging # Marketing End Date Marketing Information 9000 m UNII: CTT17582CB) Marketing Start Date Marketing Start Date	Active Ingred	ient/Active	Moiety					
POLLEN - UNII:65M888W2EG) in 1 mL DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P) POLLEN (UNII:83N78IDA7P) POLLEN - UNII:83N78IDA7P) POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - POLLEN - UNII:83N78IDA7P) POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - POLLEN - UNII:83N78IDA7P) POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS FOLLEN - POA PRATENSIS POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:8408067HOA) AGROSTIS GIGANTEA AGROSTIS GIGANTEA POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM POLLEN - UNII:85X8040C32I) So00 (PNU oDORATUM POLLEN - 0.05 g in 1 mL Inactive Ingredients Ingredient Name Strength SoDiUM HYDROXIDE (UNII: TGN4M9CD7R) 0.05 g in 1 mL SoDiUM HYDROXIDE (UNII: 55X04QC32I) 0.01 g in 1 mL PHENOL (UNII: 339NCC44TV) 0.000 amL in 1 mL SODIUM CHLORIDE (UNII: 451W47IQ8X) HYDROCHLORIC ACID (UNII: 0TT17582CB) Marketing Start Date Marketing End Date Marketing Information In 1 VIAL; Type 0: Not a Combination Imactive Ingretient Marketing End Date		Ingre	dient Name		Basis of St	rength	Strength	
POLLEN - UNII:83N78IDA7P) POLLEN in 1 mL POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T) POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - In 1 mL POA PRATENSIS POLLEN SOUD (PNU in 1 mL AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) AGROSTIS GIGANTEA AGROSTIS GIGANTEA POLLEN - UNII:ZKIK19R45Y) AGROSTIS GIGANTEA POLLEN - UNII:ZKIK19R45Y) AGROSTIS GIGANTEA ANTHOXANTHUM ODORATUM POLLEN (UNII: ZKIK19R45Y) ANTHOXANTHUM ODORATUM POLLEN 5000 (PNU in 1 mL Inactive Ingredients Ingredient Name Strength POTASSIUM ALUMINATE (UNII: TGN4M9CD7R) 0.05 g in 1 mL 0.004 mL in 1 mL SODUM HYDROXIDE (UNII: 55X04QC32I) 0.004 mL in 1 mL 0.004 mL in 1 mL PHENOL (UNII: 339NCG44TV) 0.004 mL in 1 mL 0.009 g in 1 mL SODUM CHLORIC ACID (UNII: 451W47IQ8X) 0.009 g in 1 mL 0.009 g in 1 mL Packaging Item Code Package Description Marketing Start Date Marketing End Date Marketing Information In 1 VIAL; Type 0: Not a Combination Product In 1 VIAL; Type 0: Not a Combination In 1		•	II: 65M88RW2EG) (PHLEUM PRATE	NSE		NSE	5000 [PNU] in 1 mL	
UNII:SCB8J7LS3T) IN A GROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA AGROSTIS GIGANTEA			(UNII: 83N78IDA7P) (DACTYLIS GI	LOMERATA		IERATA	5000 [PNU] in 1 mL	
POLLEN - UNII:HU8V6E7HOA) IN 1 mL ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y) (ANTHOXANTHUM		OLLEN (UNII: S	CB8J7LS3T) (POA PRATENSIS PO	LLEN -	POA PRATENSIS	POLLEN	5000 [PNU] in 1 mL	
ODORATUM POLLEN - UNII: 2KIK19R45Y) ODORATUM POLLEN 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) 0.009 g 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 Marketing Information Marketing Start Date Marketing Start Date			NII: HU8V6E7HOA) (AGROSTIS GI	GANTEA		ANTEA	5000 [PNU] in 1 mL	
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) 0.009 g in 1 mL Packaging Marketing Start Marketing End Date 1 NDC:0268-8006- 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Image: Start Star				OXANTHUM		-	5000 [PNU] in 1 mL	
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) 0.009 g in 1 mL Packaging Marketing Start Marketing End Date 1 NDC:0268-8006- 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Image: Start Star								
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R) 0.05 g in 1 mL SODUM HYDROXIDE (UNII: 55X04QC32I) 0.01 g in 1 mL PHENOL (UNII: 339NCG44TV) 0.004 mL in 1 mL SODUM CHLORIDE (UNII: 451W47IQ8X) 0.009 g in 1 mL HYDROCHLORIC ACID (UNII: QTT17582CB) 0.009 g in 1 mL Packaging Marketing Start # Item Code Package Description NDC: 0268-8006- 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Product Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	Inactive Ingre					<u>.</u>		
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) 0.009 g in 1 mL # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:0268-8006- 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Image: Comparison of the start Date Marketing Start Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date					0.05 a ia		jth	
PHENOL (UNII: 339NCG44TV) 0.004 mL in 1 mL SODIUM CHLORIDE (UNII: 451W47IQ8X) 0.009 g in 1 mL HYDROCHLORIC ACID (UNII: QTT17582CB) 0.009 g in 1 mL # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:0268-8006- S.5 mL in 1 VIAL; Type 0: Not a Combination 05 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Image: Category Marketing Start Date Marketing Start Date		•						
Solum CHLORIDE (UNII: 451W47IQ8X) 0.009 g in 1 mL HYDROCHLORIC ACID (UNII: QTT17582CB) 0.009 g in 1 mL Packaging Item Code Package Description Marketing Start Date Marketing Code8-8006- 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Image: Comparison of the co		•						
HYDROCHLORIC ACID (UNII: QTT17582CB) Packaging # Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:0268-8006- 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Image: Colspan="4">Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" Image: Colspan="4" <th cols<="" td=""><td></td><td></td><td>108X)</td><td></td><td>0.009 g ii</td><td>n 1 mL</td><td></td></th>	<td></td> <td></td> <td>108X)</td> <td></td> <td>0.009 g ii</td> <td>n 1 mL</td> <td></td>			108X)		0.009 g ii	n 1 mL	
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 Image: Comparison of the start Date Marketing End Date Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date								
# 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 Image: Comparison of Combination Image: Comparison of Combination Marketing Image: Comparison of Combination Number or Monograph Citation Marketing Start Date Application Number or Monograph Citation Marketing Start Date Marketing End Date								
# Item Code Package Description Date Date 1 NDC:0268-8006- 05 5.5 mL in 1 VIAL; Type 0: Not a Combination Product Date Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing Start Date	Packaging							
Image: Open decimal open d	# Item Code	Рас	kage Description	Mark	-			
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date			AL; Type 0: Not a Combination					
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date								
Category Citation Date Date	Marketing	Informat	ion					
BLA BLA103753 01/15/1975 05/25/2023	aceg				ulcation Ctart	Mark	oting End	
	Marketing	Applicat		n Mai		Mark		

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

#	ltem 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				
M	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 Strengt			gth Strength		

			975	05/24/20	
Marketing Category	Application Number or Monog Citation	raph Mark	eting Start Date		eting End Date
Marketing	Information				
NDC:0268-8010- 05	5.5 mL in 1 VIAL; Type 0: Not a Combinati Product	on			
# Item Code	Package Description		ing Start ate		ting End ate
Packaging					
HYDROCHLORIC A	CID (UNII: QTT17582CB)				
	E (UNII: 451W47IQ8X)		0.009 g ii		
PHENOL (UNII: 3391			0.01 g in 0.004 mL		
	POTASSIUM ALUMINATE (UNII: TGN4M9CD7R) 0.05 g in 1 mL ODIUM HYDROXIDE (UNII: 55X04QC32I) 0.01 g in 1 mL				
	Ingredient Name			Strengt	th
nactive Ingre					
ODORATUM POLLEN	DDORATUM POLLEN (UNII: 2KIK19R45Y) (/ - UNII:2KIK19R45Y)	an i huxan i hum	ANTHOXANTHU ODORATUM PO		100 [PNU] in 1 mL
POLLEN - UNII:HU8V	,		AGROSTIS GIG		100 [PNU] in 1 mL
JNII:SCB8J7LS3T)	DLLEN (UNII: SCB8J7LS3T) (POA PRATENSI:		POA PRATENSIS		100 [PNU] in 1 mL
POLLEN - UNII:83N78	,		DACTYLIS GLON POLLEN	MERATA	100 [PNU] in 1 mL
POLLEN - UNII:65M8	BRW2EG)	PRATENSE	POLLEN		100 [PNU] in 1 mL

B GRASS MIX					
promus inermis pollen, cynodon dactylon, cynodon dactylon injection, solution					
Product Information					
Product Type	NON-STANDARDIZED ALLERGENIC	ltem	Code (Source)	NDC:0268-8001	
Route of Administration	SUBCUTANEOUS				
Active Ingredient/Active	Moiety				
Ingre	dient Name		Basis of Strength	Strength	
CYNODON DACTYLON WHOLE (UWHOLE - UNII:2Q8MR21NHK)	INII: 2Q8MR21NHK) (CYNODON DACTYL	ON	CYNODON DACTYLON WHOLE	20000 [PNU] in 1 mL	
BROMUS INERMIS POLLEN (UNII: UNII: 766QT72BK6)	766QT72BK6) (BROMUS INERMIS POLL	EN -	BROMUS INERMIS POLLEN	20000 [PNU] in 1 mL	
SORGHUM HALEPENSE POLLEN POLLEN - UNII:577VA5B4HP)	(UNII: 577VA5B4HP) (SORGHUM HALEPI	ENSE	SORGHUM HALEPENSE POLLEN	20000 [PNU] in 1 mL	

Inactive Ingre	dients		
	Ingredient Name		Strength
POTASSIUM ALUM	INATE (UNII: TGN4M9CD7R)	0.	05 g in 1 mL
SODIUM HYDROXI	DE (UNII: 55X04QC32I)	0.	01 g in 1 mL
PHENOL (UNII: 339	NCG44TV)	0.	004 mL in 1 mL
SODIUM CHLORID	E (UNII: 451W47IQ8X)	0.	009 g in 1 mL
HYDROCHLORIC A	CID (UNII: QTT17582CB)		
Dockoging			
Packaging # Item Code	Package Description	Marketing St Date	
# Item Code	Package Description 32 mL in 1 VIAL; Type 0: Not a Combination Product	Marketing St Date	art Marketing End Date
 # Item Code 1 NDC:0268-8001- 30 	32 mL in 1 VIAL; Type 0: Not a Combination Product		
 # Item Code 1 NDC:0268-8001- 30 Marketing 	32 mL in 1 VIAL; Type 0: Not a Combination Product	Date	Date
 # Item Code 1 NDC:0268-8001- 30 	32 mL in 1 VIAL; Type 0: Not a Combination Product		Date

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	Streng	gth		
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R)	0.05 g in 1 mL			

SODIUM HYDRC	XIDE (UNII: 55X04QC32I)	0.01 g	in 1 mL	
PHENOL (UNII: 339NCG44TV)			0.004 mL in 1 mL	
SODIUM CHLORIDE (UNII: 451W47IQ8X)			j in 1 mL	
HYDROCHLORIC	CACID (UNII: QTT17582CB)			
Packaging				
# Item Cod	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:0268-800	4- 32 mL in 1 VIAL; Type 0: Not a Combination Product	on		
Marketing	g Information			
Marketing Category	Application Number or Monog Citation	raph Marketing Star Date	t Marketing End Date	
		01/15/1975		

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

Product Information					
Product Type	NON-STANDARDIZED ALLERGENIC	ltem 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: ZO990027NP) (POA PRATENSIS - UNII:ZO990027NP)	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			

H١	HYDROCHLORIC ACID (UNII: QTT17582CB)						
P	ackaging						
#	ltem 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 CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date						
BL	A	BLA103753	01/15/1975				

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

Product Information					
Product Type	NON-STANDARDIZED ALLERGENIC	ltem 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: ZO990027NP) (POA PRATENSIS - UNII:ZO990027NP)	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)				

Pa	ickaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0268-8009- 10	10.5 mL in 1 VIAL; Type 0: Not a Combination Product		
Μ	arketing	Information		
Μ	arketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

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	ltem	Code (Source)	NDC:0268-8011	
Route of Administration	SUBCUTANEOUS				
Active Ingredient/Active	Moiety				
			Basis of		
Ingre	dient Name		Strength	Strength	
PHLEUM PRATENSE (UNII: 0P46LF UNII:0P46LFE4VC)	E4VC) (PHLEUM PRATENSE -		PHLEUM PRATENSE	10000 [PNU] in 1 mL	
DACTYLIS GLOMERATA (UNII: 918 UNII:9182Z61D36)	32Z 61D36) (DACTYLIS GLOMERATA -		DACTYLIS GLOMERATA	10000 [PNU] in 1 mL	
POA PRATENSIS (UNII: Z0990027	NP) (POA PRATENSIS - UNII:ZO990027	NP)	POA PRATENSIS	10000 [PNU] in 1 mL	
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA OLLEN OLL					
FESTUCA PRATENSIS (UNII: IOL9HH67Y9) (FESTUCA PRATENSIS - UNII:IOL9HH67Y9) FESTUCA PRATENSIS -					
LOLIUM PERENNE (UNII: 7C82Y2E	F9V) (LOLIUM PERENNE - UNII:7C82Y2E	F9V)	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)				

Pa	Packaging						
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
	NDC:0268-8011- 30	32 mL in 1 VIAL; Type 0: Not a Combination Product					
Μ	arketing I	nformation					
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date							
BLA	٩	BLA103753	01/15/1975	05/24/2023			

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: ZO990027NP) (POA PRATENSIS - UNII:ZO990027NP)	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

#	ltem 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		
Μ	larketing l	nformation		
M	larketing l Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
M	Marketing Category	Application Number or Monograph	-	-

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

Product Information					
Product Type	NON-STANDARDIZED ALLERGENIC	ltem 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: ZO990027NP) (POA PRATENSIS - UNII:ZO990027NP)	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)	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0268-8013- 10 Product 10.5 mL in 1 VIAL; Type 0: Not a Combination					
2	NDC:0268-8013- 30	32 mL in 1 VIAL; Type 0: Not a Combination Product				
Marketing Information						
M	larketing	Information				
M	larketing Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
№ BL	Marketing Category	Application Number or Monograph	-			

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: ZO990027NP) (POA PRATENSIS - UNII:ZO990027NP)	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)			

titem Code						
	Pa	ckage Description	Marl	keting Start Date	Mar	keting End Date
NDC:0268-8014	I- 10.5 mL in 1 V Product	/IAL; Type 0: Not a Combination				
2 NDC:0268-8014	I- 32 mL in 1 VIA Product	L; Type 0: Not a Combination				
Marketing	Informat	ion				
Marketing Category		tion Number or Monograph Citation	Ма	rketing Start Date	Ма	rketing End Date
BLA	BLA103753		01/15	5/1975	05/24	
		odon dactylon, dactylis glome sis, sorghum halepense polle		-	5, 10110	in perenne
hleum pratens	se, poa praten	sis, sorghum halepense polle	en inje	ction, solution		
Product Info	rmation					
Product Type		NON-STANDARDIZED ALLERGENIC	lte	m Code (Source	e) N	DC:0268-801
Route of Administration SUBCUTANEOUS						
	nistration	SUBCUTANEOUS				
A						
Active Ingree	dient/Active	Moiety				
-	dient/Active Ingre	Moiety dient Name		Basis of Stre	_	Strength
- CYNODON DACT	dient/Active Ingre YLON WHOLE (1	Moiety	CTYLON	Basis of Stre	_	
WHOLE - UNII:2Q8	dient/Active Ingre YLON WHOLE (MR21NHK) PENSE POLLEN	Moiety dient Name		CYNODON DACT WHOLE	YLON	Strength 10000 [PNU] in 1 mL
CYNODON DACT WHOLE - UNII:2Q8I SORGHUM HALEI POLLEN - UNII:577 PHLEUM PRATEN	dient/Active Ingre YLON WHOLE (I MR21NHK) PENSE POLLEN VA5B4HP)	Moiety dient Name JNII: 2Q8MR21NHK) (CYNODON DAC		CYNODON DACT WHOLE E SORGHUM HALE	YLON PENSE	Strength 10000 [PNU] in 1 mL 10000 [PNU]
CYNODON DACT WHOLE - UNII:2Q8I SORGHUM HALEI POLLEN - UNII:577 PHLEUM PRATEN UNII:0P46LFE4VC) DACTYLIS GLOM	dient/Active Ingre YLON WHOLE (1 MR21NHK) PENSE POLLEN VA5B4HP) ISE (UNII: 0P46LF ERATA (UNII: 918	Moiety dient Name JNII: 2Q8MR21NHK) (CYNODON DAC (UNII: 577VA5B4HP) (SORGHUM HA	LEPENSE	CYNODON DACT WHOLE E SORGHUM HALE POLLEN	YLON PENSE ISE	Strength 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU]
CYNODON DACT WHOLE - UNII:2Q8I SORGHUM HALEI POLLEN - UNII:577 PHLEUM PRATEN UNII:0P46LFE4VC) DACTYLIS GLOM UNII:9182Z61D36)	dient/Active Ingre YLON WHOLE (I MR21NHK) PENSE POLLEN VA5B4HP) ISE (UNII: 0P46LF ERATA (UNII: 918	Moiety dient Name JNII: 2Q8MR21NHK) (CYNODON DAC (UNII: 577VA5B4HP) (SORGHUM HA E4VC) (PHLEUM PRATENSE -	LEPENS I	CYNODON DACT WHOLE SORGHUM HALE POLLEN PHLEUM PRATEN	YLON PENSE ISE	Strength 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU]
CYNODON DACT WHOLE - UNII:2Q8I SORGHUM HALEI POLLEN - UNII:577 PHLEUM PRATEN UNII:0P46LFE4VC) DACTYLIS GLOM UNII:9182Z61D36) POA PRATENSIS AGROSTIS GIGAN	dient/Active Ingre YLON WHOLE (I MR21NHK) PENSE POLLEN VA5B4HP) ISE (UNII: 0P46LF ERATA (UNII: 918 (UNII: Z0990027 ITEA POLLEN (U	Moiety dient Name JNII: 2Q8MR21NHK) (CYNODON DAC (UNII: 577VA5B4HP) (SORGHUM HA E4VC) (PHLEUM PRATENSE - 32Z 61D36) (DACTYLIS GLOMERATA	LEPENSE - D27NP)	CYNODON DACT WHOLE SORGHUM HALE POLLEN PHLEUM PRATEN DACTYLIS GLOM	YLON PENSE ISE IERATA	Strength 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU]
CYNODON DACT WHOLE - UNII:2Q8I SORGHUM HALEI POLLEN - UNII:577 PHLEUM PRATEN UNII:0P46LFE4VC) DACTYLIS GLOM UNII:9182Z 61D36) POA PRATENSIS AGROSTIS GIGAN POLLEN - UNII:HU8	dient/Active Ingre YLON WHOLE (I MR21NHK) PENSE POLLEN VA5B4HP) ISE (UNII: 0P46LF ERATA (UNII: 918 (UNII: Z0990027 ITEA POLLEN (U V6E7HOA)	Moiety dient Name JNII: 2Q8MR21NHK) (CYNODON DAC (UNII: 577VA5B4HP) (SORGHUM HA E4VC) (PHLEUM PRATENSE - 32Z61D36) (DACTYLIS GLOMERATA	LEPENSE - D27NP)	 CYNODON DACT WHOLE SORGHUM HALE POLLEN PHLEUM PRATEN DACTYLIS GLOM POA PRATENSIS AGROSTIS GIGA 	YLON PENSE ISE IERATA NTEA	Strength 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL
CYNODON DACT WHOLE - UNII:2Q8I SORGHUM HALEI POLLEN - UNII:577 PHLEUM PRATEN UNII:0P46LFE4VC) DACTYLIS GLOM UNII:9182Z 61D36) POA PRATENSIS AGROSTIS GIGAN POLLEN - UNII:HUE FESTUCA PRATE UNII:IOL9HH67Y9)	dient/Active Ingre YLON WHOLE (I MR21NHK) PENSE POLLEN VA5B4HP) ISE (UNII: 0P46LF ERATA (UNII: 918 (UNII: ZO990027 ISEA POLLEN (U SV6E7HOA) NSIS (UNII: 10L9F	Moiety dient Name JNII: 2Q8MR21NHK) (CYNODON DAC (UNII: 577VA5B4HP) (SORGHUM HA E4VC) (PHLEUM PRATENSE - 32Z 61D36) (DACTYLIS GLOMERATA NP) (POA PRATENSIS - UNII:ZO9900 INII: HU8V6E7HOA) (AGROSTIS GIGA	LEPENSE - D27NP) ANTEA	 CYNODON DACT WHOLE SORGHUM HALE POLLEN PHLEUM PRATEN DACTYLIS GLOM POA PRATENSIS AGROSTIS GIGA POLLEN FESTUCA PRATE 	YLON PENSE ISE IERATA NTEA NSIS	Strength 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL
CYNODON DACT WHOLE - UNII:2Q8I SORGHUM HALEI POLLEN - UNII:577 PHLEUM PRATEN UNII:0P46LFE4VC) DACTYLIS GLOM UNII:9182Z 61D36) POA PRATENSIS AGROSTIS GIGAN POLLEN - UNII:HU8 FESTUCA PRATE UNII:IOL9HH67Y9)	dient/Active Ingre YLON WHOLE (I MR21NHK) PENSE POLLEN VA5B4HP) ISE (UNII: 0P46LF ERATA (UNII: 918 (UNII: ZO990027 ISEA POLLEN (U SV6E7HOA) NSIS (UNII: 10L9F	Moiety dient Name JNII: 2Q8MR21NHK) (CYNODON DAC (UNII: 577VA5B4HP) (SORGHUM HA E4VC) (PHLEUM PRATENSE - 32Z61D36) (DACTYLIS GLOMERATA 'NP) (POA PRATENSIS - UNII:ZO9900 INII: HU8V6E7HOA) (AGROSTIS GIGA H67Y9) (FESTUCA PRATENSIS -	LEPENSE - D27NP) ANTEA	 CYNODON DACT WHOLE SORGHUM HALE POLLEN PHLEUM PRATEN DACTYLIS GLOM POA PRATENSIS AGROSTIS GIGA POLLEN FESTUCA PRATE 	YLON PENSE ISE IERATA NTEA NSIS	Strength 10000 [PNU] in 1 mL 10000 [PNU] in 1 mL

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								
#	ltem 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				
BL	A	BLA103753	01/15/1975	05/24/2023				

SODIUM HYDROXIDE (UNII: 55X04QC32I)

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						
Basi	s of Strength	Strength				
		20000 [PNU] in 1 mL				
5B4HP) (SORGHUM HALEPENSE SORGHUM HALEPENSE 2 POLLEN i		20000 [PNU] in 1 mL				
PHLEU	JM PRATENSE	20000 [PNU] in 1 mL				
DACT	YLIS GLOMERATA	20000 [PNU] in 1 mL				
POA P	RATENSIS	20000 [PNU] in 1 mL				
		20000 [PNU] in 1 mL				
FESTU	JCA PRATENSIS	20000 [PNU] in 1 mL				
LOLIUM PERENNE		20000 [PNU] in 1 mL				
Inactive Ingredients						
	Strei	ngth				
POTASSIUM ALUMINATE (UNII: TGN4M9CD7R) 0.05 g in 1 mL						
	CYNO WHOL SORG POLLE PHLEU DACT POA P AGRO POLLE FESTU LOLIU	POLLEN PHLEUM PRATENSE DACTYLIS GLOMERATA POA PRATENSIS AGROSTIS GIGANTEA POLLEN FESTUCA PRATENSIS LOLIUM PERENNE Stree				

0.01 g in 1 mL

PH	ENOL (UNII: 339N	ICG44TV)	0.0	0.004 mL in 1 mL		
so	DIUM CHLORIDE	0.0	009 g in 1 mL			
HYDROCHLORIC ACID (UNII: QTT17582CB)						
Pa	ackaging					
#	ltem Code	Package Description	Marketing Sta Date	art Marketing End Date		
	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 S Date	itart Marketing End Date		
BL	A	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: ZO990027NP) (POA PRATENSIS - UNII:ZO990027NP)	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			

nactive Ingre	dients						
	Ingredient Name		Strength				
POTASSIUM ALUM	0.05 g	in 1 mL					
	DE (UNII: 55X04QC32I)	0.01 g	in 1 mL				
PHENOL (UNII: 3391	NCG44TV)	0.004 m	nL in 1 mL				
	E (UNII: 451W47IQ8X)	0.009 g	in 1 mL				
IYDROCHLORIC A	CID (UNII: QTT17582CB)						
	Packaging						
Packaging							
	Package Description	Marketing Start Date	Marketing End Date				
# Item Code	Package Description 32 mL in 1 VIAL; Type 0: Not a Combination Product	-	Marketing End Date				
# Item Code NDC:0268-8017-	32 mL in 1 VIAL; Type 0: Not a Combination	-	-				
 # Item Code 1 NDC:0268-8017- 30 	32 mL in 1 VIAL; Type 0: Not a Combination	-	-				
1 NDC:0268-8017- 30	32 mL in 1 VIAL; Type 0: Not a Combination Product	-	Date				

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			

Inactive Ingredients								
		Ingredient Name			Strength			
PC	TASSIUM ALUM	INATE (UNII: TGN4M9CD7R)	0.0	005 g ir	n 1 mL			
sc	DIUM HYDROXI	DE (UNII: 55X04QC32I)	0.0	01 g in	1 mL			
PHENOL (UNII: 339NCG44TV) 0.00			0.004 mL in 1 mL					
SODIUM CHLORIDE (UNII: 451W47IQ8X) 0.009 g in 1 mL				n 1 mL				
ΗY	DROCHLORIC A	CID (UNII: QTT17582CB)						
Packaging								
#	ltem Code	Package Description	Marketing St Date	tart	Marketing End Date			

#	ltem 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					
M	Marketing Information						
	Marketing	Application Number or Monograph	Marketing Start	Marketing End			
	Category	Citation	Date	Date			

MIXED RAGWEED

ambrosia artemisiifolia, ambrosia trifida pollen injection, solution

Product Information						
NON-STANDARDIZED ALLERGENIC	Item Co	de (Source)	NDC:0268-8057			
SUBCUTANEOUS						
Maiaty						
MOIELY						
Ingredient Name Basis of Strength Strength						
I: 9W34L2CQ9A) (AMBROSIA ARTEMISIIF			10000 [PNU] in 1 mL			
II: KU1V1898XX) (AMBROSIA TRIFIDA PO			10000 [PNU] in 1 mL			
Inactive Ingredients						
redient Name		Str	ength			
GN4M9CD7R)		0.05 g in 1 ml	_			
	SUBCUTANEOUS Moiety edient Name I: 9W34L2CQ9A) (AMBROSIA ARTEMISIIF II: KU1V1898XX) (AMBROSIA TRIFIDA PO	Moiety edient Name I: 9W34L2CQ9A) (AMBROSIA ARTEMISIIFOLIA II: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN PO predient Name	SUBCUTANEOUS Item couct (source) Moiety Basis of Strength i: 9W34L2CQ9A) (AMBROSIA ARTEMISIIFOLIA AMBROSIA ARTEMISIIFOLIA II: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN AMBROSIA TRIFIDA POLLEN gredient Name Str			

SC	DIUM HYDROXI	0.01 g in 1 mL			
P۲	HENOL (UNII: 339NCG44TV)			0.004 mL in 1 mL	
sc	DIUM CHLORID	E (UNII: 451W47IQ8X)		0.009 g ir	n 1 mL
HΥ	DROCHLORIC A	CID (UNII: QTT17582CB)			
Pa	ackaging				
#	ltem Code	Package Description	Marketing 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			
Μ	larketing	Information			
	Marketing	Application Number or Monograph	Marketin	a Start	Marketing End

Marketing /	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
BLA BL	_A103753	01/15/1975	

MIXED RAGWEED

ambrosia artemisiifolia, ambrosia trifida pollen injection, solution

Product Information							
Product Type	NON-STANDARDIZED ALLERGENIC	ltem 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	AMBROSIA	20000 [PNU]
- UNII:9W34L2CQ9A)	ARTEMISIIFOLIA	in 1 mL
AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN	AMBROSIA TRIFIDA	20000 [PNU]
- UNII:KU1V1898XX)	POLLEN	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

Marketing Information			
h Marketing Start Date	Marketing End Date		
01/15/1975			
)	Date		

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

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.