BAHIA GRASS - bahia grass injection, solution ANNUAL BLUE GRASS - annual blue grass injection, solution CANADIAN BLUE GRASS - canadian blue grass injection, solution **BROME GRASS** - brome grass injection, solution **CANARY GRASS** - canary grass injection, solution CORN GRASS - corn grass injection, solution COUCH QUACK GRASS - couch quack grass injection, solution GRAMA GRASS - grama grass injection, solution JOHNSON GRASS - johnson grass injection, solution CULTIVATED OAT - cultivated oat injection, solution CULTIVATED RYE - cultivated rye injection, solution GIANT WILD RYE - giant wild rye injection, solution ITALIAN RYE GRASS - italian rye grass injection, solution SALT GRASS - salt grass injection, solution VELVET GRASS - velvet grass injection, solution CULTIVATED WHEAT - cultivated wheat injection, solution WEST WHEAT GRASS - west wheat grass injection, solution SOFT CHEAT BROME - soft cheat brome injection, solution SMOOTH BROME - smooth brome injection, solution Nelco Laboratories, Inc.

Allergenic Extract

WARNING

Diagnostic and therapeutic allergenic extracts are intended to be administered by a physician who is an allergy specialist and experienced in allergenic diagnostic testing and immunotherapy and the emergency care of anaphylaxis.

This product should not be injected intravenously. Deep subcutaneous routes have been safe. Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and/or death. (See Adverse Reactions)

Serious adverse reactions should be reported to Nelco Laboratories immediately and a report filed to: MedWatch, The FDA Medical Product Problem Reporting Program, at 5600 Fishers Lane, Rockville, Md. 20852-9787, call 1-800-FDA-1088.

Extreme caution should be taken when using allergenic extracts for patients who are taking betablocker medications. In the event of a serious adverse reaction associated with the use of allergenic extracts, patients receiving beta-blockers may not be responsive to epinephrine or inhaled brochodialators.⁽¹⁾(See Precautions)

Allergenic extracts should be used with caution for patients with unstable or steroid-dependent asthma or underlying cardiovascular disease. **(See Contraindications)**

DESCRIPTION

Allergenic extracts are sterile solutions consisting of the extractable components from various biological sources including pollens, inhalants, molds, animal epidermals and insects. Aqueous extracts are prepared using cocas fluid containing NaCl 0.5%, NaHCO3 0.0275%, WFI, preservative 0.4% Phenol. Glycerinated allergenic extracts are prepared with cocas fluid and glycerin to produce a 50% (v/v) allergenic extract. Allergenic Extracts are supplied as concentrations designated as protein nitrogen units (PNU) or weight/volume (w/v) ratio. Standardized extracts are designated in

Bioequivalent Allergy Units (BAU) or Allergy Units (AU). (See product insert for standardized extracts)

For diagnostic purposes, allergenic extracts are to be administered by prick-puncture or intradermal routes. Allergenic extracts are administered subcutaneously for immunotherapy injections.

CLINICAL PHARMACOLOGY

The pharmacological action of allergenic extracts used diagnostically is based on the liberation of histamine and other substances when the allergen reacts with IgE antibodies attached to the mast cells. When allergenic extracts are used for immunotherapy, the effect is an increase in immunoglobulin G (IgG) and an increased T suppresser lymphocyte which interferes with the allergic response.⁽²⁾ With repeated administration of allergenic extracts changes develop in regards to IgG and IgE production and mediator-releasing cells. The histamine release response is reduced in some patients.

INDICATIONS AND USAGE

Allergenic extracts are indicated for use in diagnostic testing and as part of a treatment regime for allergic disease, as established by allergy history and skin test reactivity.

Allergenic extracts are indicated for the treatment of allergen specific allergic disease for use as hyposensitization or immunotherapy when avoidance of specific allergens can not be attained. The use of allergenic extracts for therapeutic purpose has been established by well-controlled clinical studies. Allergenic extracts may be used as adjunctive therapy along with pharmacotherapy which includes antihistamines, corticosteroids, and cromoglycate, and avoidance measures. Allergenic extracts for therapeutic use should be given using only the allergen selection to which the patient is allergic, has a history of exposure and are likely to be exposed to again.

CONTRAINDICATIONS

Allergenic extracts should not be used if the patient has asthma, cardiovascular disease, emphysema, diabetes, bleeding diathesis or pregnancy, unless a specific diagnosis of type 1 allergic disease is made based on skin testing and the benefits of treatment outweigh the risks of an adverse reaction during testing or treatment. Allergenic extracts are not indicated for use in patients who are not clinically allergic or who are not skin reactive to an allergen. Allergenic extracts should be discontinued or the concentration of potency substantially reduced in patients who experience unacceptable adverse reactions.

WARNINGS

DO NOT INJECT INTRAVENOUSLY.

Epinephrine 1:1000 should be available.

Concentrated extracts must be diluted with sterile diluent prior to first use on a patient for treatment or intradermal testing. All concentrates of glycerinated allergenic extracts have the ability to cause serious local and systemic reactions including death in sensitive patients. Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and /or death.⁽⁴⁾(*See Adverse Reactions*) An allergenic extract should be temporarily withheld from patients or the dose of the extract adjusted downward if any of the following conditions exist: (1) Severe symptoms of rhinitis and/or asthma (2) Infections or flu accompanied by fever and (3) Exposure to excessive amounts of clinically relevant allergen prior to a scheduled injection. When switching patients to a new lot of the same extract the initial dose should be reduced 3/4 so that 25% of previous dose is administered.

PRECAUTIONS

GENERAL: Epinephrine 1:1000 should be available as well as personnel trained in administering

emergency treatment. Allergenic Extracts are not intended for intravenous injections. For safe and effective use of allergenic extracts, sterile diluents, sterile vials, sterile syringes should be used and aseptic precautions observed when making a dilution and/or administering the allergenic extract injection. A sterile tuberculin syringe graduated in 0.1 ml units to measure each dose for the prescribed dilution should be used. To reduce the risk of an occurrence of adverse reactions, begin with a careful personal history plus a physical exam. Confirm your findings with scratch or intradermal skin testing.

Standardized extracts are those labeled in AU/ml units or BAU/ml units. Standardized extracts are not interchangeable with extracts previously labeled as wt/vol or PNU/ml. Before administering a standardized extract, read the accompanying insert contained with standardized extracts.

Information for Patients: All concentrates of allergenic extracts have the ability to cause serious local and systemic reactions including death in sensitive patients. Patients should be informed of this risk prior to skin testing and immunotherapy. Patients should be instructed to recognize adverse reaction symptoms that may occur and to report all adverse reactions to a physician. Patients should be instructed to remain in the office for 30 minutes during testing using allergenic extracts and at least 30 minutes after therapeutic injections using allergenic extracts.

DRUG INTERACTIONS: Some drugs may affect the reactivity of the skin; patients should be instructed to avoid medications, particularly antihistamines and sympathomimetic drugs, for at least 24 hours prior to skin testing. Antihistamines and Hydroxyzine can significantly inhibit the immediate skin test reactions as they tend to neutralize or antagonize the action of histamine.⁽³⁾ This effect has been primarily documented when testing was performed within 1 to 2 hours after drug ingestion. Partial inhibition of the skin test reaction had been observed for longer periods. Epinephrine injection inhibits the immediate skin test reactions for several hours. Patients on delayed absorption antihistamine tablets should be free of such medication for 48 hours before testing. Patients using Astemizole (Hismanal) may experience prolonged suppression and should be free from such medication for up to 6 to 8 weeks prior to testing. Refer to package insert from an applicable long acting antihistamine manufacturer for additional information.

Extreme caution should be taken when using allergenic extracts on patients who are taking betablockers. Patients on non-selective beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

Carcinogenesis, mutagenesis, impairment of fertility:

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

Pregnancy: Category C: Animal reproduction studies have not been conducted with Allergenic Extracts. It is not known whether allergenic extracts can cause fetal harm when administered to pregnant women or can affect reproduction capacity. Allergenic extracts should be given to pregnant women only if clearly needed.

Nursing Mothers: It is not known whether this drug appears in human milk. Because many drugs are detected in human milk, caution should be exercised when Allergenic Extracts are administered to a nursing woman. There are no current studies on extract components in human milk, or their effect on the nursing infant.

Pediatric Use: Allergenic extracts have been used in children over two years of age.⁽⁵⁾

ADVERSE REACTIONS

Adverse systemic reactions usually occur within minutes and consist primarily of allergic symptoms such as: generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema, itching of nose and throat, breathlessness, dyspnea, coughing, hypotension and marked perspiration. Less commonly, nausea, emesis, abdominal cramps, diarrhea and uterine contractions may occur. Severe

reactions may cause anaphylaxis or shock and loss of consciousness and rarely death.

The treatment of systemic allergic reactions is dependent upon the system complex. Antihistamines may offer relief of recurrent urticaria, associated skin reactions and gastrointestinal symptoms. Corticosteroids may provide benefit if symptoms are prolonged or recurrent. **(See Overdose section)**

Local Reactions consisting of erythema, itching, swelling tenderness and sometimes pain may occur at the injection site. These reactions may appear within a few minutes to hours and persist for several days. Local cold applications and oral antihistamines may be effective treatment. For marked and prolonged local reactions the use of antihistamines or anti-inflammatory medications may be dictated. **Serious adverse reactions** should be reported to Nelco Laboratories immediately and a report can be filed to: **MedWatch, The FDA Medical Product Problem Reporting Program, at 5600 Fishers Lane, Rockville, MD 20852-9787, call 1-800-FDA-1088.**

OVERDOSAGE

Overdose can cause both local and systemic reactions. An overdose may be prevented by careful observation and questioning of the patient about the previous injection.

If systemic or anaphylactic reaction, does occur, apply a tourniquet above the site of injection and inject intramuscularly or subcutaneously 0.3 to 0.5ml of 1:1000 Epinephrine Hydrochloride into the opposite arm. The dose may be repeated in 5-10 minutes if necessary. Loosen the tourniquet at least every 10 minutes. The Epinephrine Hydrochloride 1:1000 dose for infants to 2 years is 0.05 to 0.1 ml, for children 2 to 6 years it is 0.15 ml, for children 6-12 years it is 0.2 ml.

Patients unresponsive to Epinephrine may be treated with Theophylline. Studies on asthmatic subjects reveal that plasma concentrations of Theophylline of 5 to 20 μ g/ml are associated with therapeutic effects. Toxicity is particularly apparent at concentrations greater than 20 μ g/ml. A loading dose of Aminophylline of 5.8 mg/kg intravenously followed by 0.9 mg/kg per hour results in plasma concentrations of approximately 10 μ g/ml for patients not previously receiving theophylline. (Mitenko and Ogilive, Nicholoson and Chick,1973)

Other beta-adrenergic drugs such as Isoproterenol, Isoetharine, or Albuterol may be used by inhalation. The usual dose to relieve broncho-constriction in asthma is 0.5 ml of the 0.5% solution for Isoproterenol HCl. The Albuterol inhaler delivers approximately 90 mcg of Albuterol from the mouthpiece. The usual dosage for adults and children would be two inhalations repeated every 4-6 hours. Isoetharine supplied in the Bronkometer unit delivers approximately 340 mcg Isoetharine. The average dose is one to two inhalations. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require oxygen, intubation and the use of life support systems.

DOSAGE AND ADMINISTRATION

General Precautions

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

The dosage of allergenic extracts is dependent upon the purpose of the administration. Allergenic extracts can be administered for diagnostic use or for therapeutic use.

When allergenic extracts are administered for diagnostic use, the dosage is dependent upon the method used. Two methods commonly used are scratch testing and intradermal testing. Both types of tests result in a wheal and flare response at the site of the test which usually develops rapidly and may be read in 20-30 minutes.

Diagnostic Use: Scratch Testing Method

Scratch testing is considered a simple and safe method although less sensitive than the intradermal test.

Scratch testing can be used to determine the degree of sensitivity to a suspected allergen before using the intradermal test. This combination lessens the severity of response to an allergen which can occur in a very sensitive patient.

The most satisfactory testing site is the patient's back or volar surface of the arms from the axilla to 2.5 or 5cm above the wrist, skipping the anti-cubital space. If using the back as a testing site, the most satisfactory area are from the posterior axillary fold to 2.5 cm from the spinal column, and from the top of the scapula to the lower rib margins.

Allergenic extracts for diagnostic use are to be administered in the following manner: To scratch surface of skin, use a circular scarifier. **Do not draw blood.** Tests sites should be 4 cm apart to allow for wheal and flare reaction. 1-30 scratch tests may be done at a time. A separate sterile scratch instrument is to be used on each patient to prevent transmission of homologous serum hepatitis or other infectious agents from one patient to another.

The recommended usual dosage for Scratch testing is one drop of allergen applied to each scratch site. **Do not let dropper touch skin.** Always apply a control scratch with each test set. Sterile Diluent (for a negative control) is used in exactly the same way as an active test extract. Histamine may be used as a positive control. Scratch or prick test sites should be examined at 15 and 30 minutes. To prevent excessive absorption, wipe off antigens producing large reactions as soon as the wheal appears. Record the size of the reaction.

Interpretation of Scratch Test

Skin tests are graded in terms of the wheal and erythema response noted at 10 to 20 minutes. Wheal and erythema size may be recorded by actual measurement as compared with positive and negative controls. A positive reaction consists of an area of erythema surrounding the scarification that is larger than the control site. For uniformity in reporting reactions, the following system is recommended. ⁽⁶⁾

REACTION	SYMBOL	CRITERIA
Negative	-	No wheal. Erythema absent or very slight (not more than 1 mm diameter).
One Plus	+	Wheal absent or very slight erythema present (not more than 3 mm diameter).
Two Plus	++	Wheal not more than 3mm or erythema not more than 5mm diameter.
Three Plus	+++	Wheal between 3mm and 5mm diameter, with erythema. Possible pseudopodia and itching.
Four Plus	++++	A larger reaction with itching and pain.

Diagnostic Use: Intradermal Skin Testing Method

Do not perform intradermal test with allergens which have evoked a 2+ or greater response to a Scratch test. Clean test area with alcohol, place sites 5 cm apart using separate sterile tuberculin syringe and a 25 gauge needle for each allergen. Insert needle tip, bevel up, into intracutaneous space. Avoid injecting into blood vessel, pull back gently on syringe plunger, if blood enters syringe change position of needle. The recommended dosage and range for intradermal testing is 0.05 ml of not more than 100 pnu/ml or 1:1000 w/v (only if puncture test is negative) of allergenic extract. Inject slowly until a small bleb is raised. It is important to make each bleb the same size.

Interpretation of Intradermal Test:

The patient's reaction is graded on the basis of size of wheal and flare as compared to control. Use 0.05 ml sterile diluent as a negative control to give accurate interpretation. The tests may be accurately interpreted only when the saline control site has shown a negative response. Observe patient for at least 30 minutes. Tests can be read in 15-20 minutes. Edema, erythema and presence of pseudopods, pain and itching may be observed in 4 plus reactions. For uniformity in reporting reactions the following system is recommended. ⁽⁶⁾

REACTION	SYMBOL	CRITERIA
Negative	-	No increase in size of bleb since injection. No erythema.
One Plus	+	An increase in size of bleb to a wheal not more than 5mm diameter, with associated erythema.
Two Plus	++	Wheal between 5mm and 8mm diameter with erythema.
Three Plus	+++	Wheal between 8mm and 12mm diameter with erythema and possible pseudopodia and itching or pain.
Four Plus	++++	Any larger reaction with itch and pain, and possible diffuse blush of the skin surrounding the reaction area.

Therapeutic Use: Recommended dosage & range

Check the listed ingredients to verify that it matches the prescription ordered. When using a prescription set, verify the patient's name and the ingredients listed with the prescription order. Assess the patient's physical and emotional status prior to giving as injection. Do not give injections to patients who are in acute distress. **Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.**

Dosage of allergenic extracts is a highly individualized matter and varies according to the degree of sensitivity of the patient, his clinical response and tolerance to the extract administered during the early phases of an injection regimen. The dosage must be reduced when transferring a patient from non-standardized or modified extract to standardized extract. Any evidence of a local or generalized reaction requires a reduction in dosage during the initial stages of immunotherapy as well as during maintenance therapy. After therapeutic injections patients should be observed for at least 20 minutes for reaction symptoms.

SUGGESTED DOSAGE SCHEDULE

The following schedule may act as a guide. **This schedule has not been proven to be safe or effective.** Sensitive patients may begin with smaller doses of weaker solutions and the dosage increments can be less.

STRENGTH	DOSE	VOLUME
Vial #1	1	0.05
1:100,000 w/v	2	0.10
10 pnu/ml	3	0.15

1 AU/ml	4	0.20
1 BAU/ml	5	0.30
	6	0.40
	7	0.50
Vial #2	8	0.05
1:10,000 w/v	9	0.10
100 pnu/ml	10	0.15
10 AU/ml	11	0.20
10 BAU/ml	12	0.30
	13	0.40
	14	0.50
Vial #3	15	0.05
1:1,000 w/v	16	0.10
1,000 pnu/ml	17	0.15
100 AU/ml	18	0.20
100 BAU/ml	19	0.30
	20	0.40
	21	0.50
Vial #4	22	0.05
1:100 w/v	23	0.07
10,000 pnu/ml	24	0.10
1,000 AU/ml	25	0.15
1,000 BAU/ml	26	0.20
	27	0.25
Maintenance Refill	28	0.25
1:100 w/v	29	0.25
10,000 pnu/ml	30	0.25
1,000 AU/ml	31	0.25
1,000 BAU/ml	32	0.25
subsequent doses	33	0.25

Preparation Instructions:

All dilutions may be made using sterile buffered diluent. The calculation may be based on the following ratio:

Volume desired x Concentration desired = Volume needed x Concentration available.

Example 1: If a 1:10 w/v extract is available and it is desired to use a 1:1,000 w/v extract substitute as follows:

Vd x Cd = Vn x Ca

 $10ml \ x \ 0.001 = Vn \ x \ 0.1$

0.1 ml = Vn

Using a sterile technique, remove 0.10 ml of extract from the 1:10 vial and place it into a vial containing 9.90 ml of sterile diluent. The resulting ratio will be a 10 ml vial of 1:1,000 w/v.

Example 2: If a 10,000 pnu/ml extract is available and it is desired to use a 100 pnu/ml extract substitute

as follows:

10ml x 100 = Vn x 10,000

0.1 ml = Vn

Using a sterile technique, remove 0.10 ml of extract from the 10,000 pnu/ml vial and place it into a vial containing 9.90 ml of sterile diluent. The resulting concentration will be a 10 ml vial of 100 pnu/ml.

<u>Example 3:</u> If a 10,000 AU/ml or BAU/ml extract is available and it is desired to use a 100 AU/ml or BAU/ml extract substitute as follows: Vd x Cd = Vn x Ca

10ml x 100 = Vn x 10,000

0.1 ml = Vn

Using a sterile technique, remove 0.10 ml of extract from the 10,000 AU/ml or BAU/ml vial and place it into a vial containing 9.90 ml of sterile diluent. The resulting concentration will be 10ml vial of 100 AU/ml or BAU/ml.

Intervals between doses: The optimal interval between doses of allergenic extract has not been definitely established. The amount of allergenic extract is increased at each injection by not more than 50%-100% of the previous amount and the next increment is governed by the response to the last injection. There are three generally accepted methods of pollen hyposensitizing therapy.

1. PRESEASONAL

Treatment starts each year 6 to 8 weeks before onset of seasonal symptoms. Maximal dose reached just before symptoms are expected. Injections discontinued during and following season until next year.

2. CO-SEASONAL

Patient is first treated during season with symptoms. Low initial doses are employed to prevent worsening of condition. This is followed by an intensive schedule of therapy (i.e. injections given 2 to 3 times per week). Fewer Allergists are resorting to this Co-seasonal therapy because of the availability of more effective, symptomatic medications that allow the patient to go through a season relatively symptom free.

3. PERENNIAL

Initially this is the same as pre seasonal. The allergen is administered twice weekly or weekly for about 20 injections to achieve the maximum tolerated dose. Then, maintenance therapy may be administered once a week or less frequently.

Duration of Treatment: The usual duration of treatment has not been established. A period of two or three years of injection therapy constitutes an average minimum course of treatment.

HOW SUPPLIED

Allergenic extracts are supplied with units listed as: Weight/volume (W/V), Protein Nitrogen Units (PNU/ml), Allergy Units (AU/ml) or Bioequivalent Allergy Units (BAU/ml).

Sizes:

Diagnostic Scratch: 5 ml dropper application vials

Diagnostic Intradermal: 5 ml or 10 ml vials.

Therapeutic Allergens: 5 ml, 10 ml, 50 ml multiple dose vials.

STORAGE

The expiration date of allergen extracts is listed on the container label. Store extracts upon arrival at 2°

to 8°C and keep them in this range during office use.

<u>WARRANTY</u>: We warrant that this product was prepared and tested according to the standards of the FDA and is true to label. Because of biological differences in individuals and because allergenic extracts are manufactured to be potent and because we have no control over the conditions of use, we cannot and do not warrant either a good effect or against an ill effect following use.

REFERENCES

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2 Ishizaka,K.: Cellular Events in the IgE Antibody Response. Adv. in Immuno. 23:50-75, 1976.

3. Lockey, R.F., Bukantz, S.C., Allergen Immunotherapy. New York, NY: Marcel Dekker Inc., 1991.

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5. Murray, A.B., Ferguson, A., Morrison, B., The frequency and severity of cat allergy vs dog allergy in atopic children. J. Allergy Clin. Immunolo: 72, 145-9, 1983.

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CONTAINER LABELING







BAHIA GRASS

bahia grass injection, solution

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Ite m	Code (Source)	NDO	2:36987-2266
Route of Administration	INTRADERMAL, SUBCUTANEOUS				
A	• • •				
Active Ingredient/Active Mo	lety				
Ing	redient Name		Basis of Streng	th	Strength
PASPALUM NOTATUM POLLEN (U POLLEN - UNII:V003SHB7VK)	NII: V003SHB7VK) (PASPALUM NOTATUM		PASPALUM NOTAT POLLEN	UM	40000 [PNU] in 1 mL
Inactive Ingredients					
Inactive Ingredients	Ingredient Name			:	Strength

SODIUM BICARBONATE (UNII: 8MDF5V39QO) WATER (UNII: 059QF0K00R) PHENOL (UNII: 339NCG44TV)

P	ackaging				
#	Item Code	Package Description	Marke	ting Start Date N	Marketing End Date
1	NDC:36987-2266-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-2266-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-2266-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-2266-4	50 mL in 1 VIAL, MULTI-DOSE			
N	Iarketing Infor	mation			
N	Aarketing Category	Application Number or Monograph C	itation	Marketing Start Date	Marketing End Date

Marketing Category	Application Number of Monograph Chauon	Marketing Start Date	Marketing End Date
BLA	BLA102192	08/29/1972	

ANNUAL BLUE GRASS

annual blue grass injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2275
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POA ANNUA POLLEN (UNII: 7U437HHU5C) (POA ANNUA POLLEN - UNII:7U437HHU5C)	POA ANNUA POLLEN	40000 [PNU] in 1 mL

	Inactive Ingredients	
	Ingredient Name	Strength
	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
	SODIUM BICARBONATE (UNII: 8 MDF5V39QO)	
	WATER (UNII: 059QF0KO0R)	
	PHENOL (UNII: 339NCG44TV)	
1		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2275-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2275-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2275-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2275-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Info	rmation						
Marketing Category	Applicatio	n Number or Monograph	Citation	Marke	ting Start Da	te Ma	rketing End Dat
BLA	BLA102192			08/29/1	972		
CANADIAN BL							
canadian blue grass ir	ijection, solut	ion					
Product Informati	on						
Product Type		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sourc	e) N	IDC:36987-2283
Route of Administrati	on	INTRADERMAL, SUBCUTA				-)	
Route of Achimistrati	UN						
Active Ingredient/		0					
	0	edient Name			Basis of St	rength	Strength
POA COMPRESSA POI UNII:50 HCQ 1NYV5)	L LEN (UNII: 501	HCQ1NYV5) (POA COMPRES	SSA POLLEN	-	POA COMPRE POLLEN	SSA	40000 [PNU] in 1 mL
Inactive Ingredien	its						
		Ingredient Name					Strength
SODIUM CHLORIDE (U							
SODIUM BICARBONAT		,V39QO)					
WATER (UNII: 059QF0F PHENOL (UNII: 339NCC							
FIEROE (ONII: 555NGC	J441V)						
Packaging			36.1	ing Sta	rt Date	Marke	ting End Date
	Pac	kage Description	Market				
# Item Code		kage Description IAL, MULTI-DOSE	Market				
# Item Code 1 NDC:36987-2283-1	5 mL in 1 V	• •	Market	8			
Figure 1 Figure 2 1 NDC:36987-2283-1 2 NDC:36987-2283-2 3 NDC:36987-2283-3	5 mL in 1 V 10 mL in 1 V	IAL, MULTI-DOSE	Market				
 # Item Code 1 NDC:36987-2283-1 2 NDC:36987-2283-2 	5 mL in 1 V 10 mL in 1 V 30 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE	Market				
 # Item Code 1 NDC:36987-2283-1 2 NDC:36987-2283-2 3 NDC:36987-2283-3 	5 mL in 1 V 10 mL in 1 V 30 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE VIAL, MULTI-DOSE	Market				
 # Item Code 1 NDC:36987-2283-1 2 NDC:36987-2283-2 3 NDC:36987-2283-3 4 NDC:36987-2283-4 	5 mL in 1 V 10 mL in 1 V 30 mL in 1 V 50 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE VIAL, MULTI-DOSE	Market				
 # Item Code 1 NDC:36987-2283-1 2 NDC:36987-2283-2 3 NDC:36987-2283-3 4 NDC:36987-2283-4 	5 mL in 1 V 10 mL in 1 V 30 mL in 1 V 50 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE					
 # Item Code 1 NDC:36987-2283-1 2 NDC:36987-2283-2 3 NDC:36987-2283-3 4 NDC:36987-2283-4 	5 mL in 1 V 10 mL in 1 V 30 mL in 1 V 50 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE VIAL, MULTI-DOSE			eting Start Da	te Ma	rketing End Dat

brome grass injection, solution

Product Information

Product Type		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sourc	(م	NDC:36987-2291
	an			ite in	Coue (Sourc		100.30307 2231
Route of Administrati	ION	INTRADERMAL, SUBCUTA	INEO US				
Active Ingredient/	Active Moi	ety					
	Ingi	edient Name			Basis of St	rength	Strength
BROMUS INERMIS PO UNII:766QT72BK6)	LLEN (UNII: 7)	56QT72BK6) (BROMUS INER	RMIS POLLEN -		BROMUS INEI POLLEN	RMIS	40000 [PNU] in 1 mL
Inactive Ingredien	its						
		Ingredient Name					Strength
SODIUM CHLORIDE (U	JNII: 451W47IQ	8X)					
SODIUM BICARBONAT	FE (UNII: 8 MD)	F5V39QO)					
WATER (UNII: 059QF0F							
PHENOL (UNII: 339NCC	G44TV)						
Packaging							
# Item Code	Pa	ckage Description	Marketing	g Sta	art Date	Marke	eting End Date
NDC:36987-2291-1	5 mL in 1 V	/IAL, MULTI-DOSE					
2 NDC:36987-2291-2	10 mL in 1	VIAL, MULTI-DOSE					
B NDC:36987-2291-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC:36987-2291-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Info	rmation						
Marketing Category	Applicati	on Number or Monograph	Citation M	Iarke	ting Start Da	te Ma	rketing End Da
BLA	BLA102192		08	/29/19	972		
CANARY GRAS							
Product Informati	on						
Product Type		HUMAN PRESCRIPTION DR	UG	Item	Code (Source	e) ľ	NDC:36987-2299
Route of Administrati	on	INTRADERMAL, SUBCUTA		ace in	cour (ovart)	-)	2.2300, 22 00
Route of Automisticat	IUII	INTRODUCINE, SOBCOTA					
Active Ingredient/	Active Moi	ety					
	Ingr	edient Name			Basis of S	trength	ı Strengtl
	CEA POLLEN	(UNII: FAY1Y90VJ9) (PHALA	RIS ARUNDINA				40000 [PNU
POLLEN - UNII:FAY1Y90	VJ9)				ARUNDINACE	A POLLE	IN in 1 mL
Inactive Ingredien					ARUNDINACE	A POLLE	IN in 1 mL

		Ingredient Name					Strength
SODIUM CHLORIDE (U	NII: 451W47IO	<u> </u>					
SODIUM BICARBONAT							
WATER (UNII: 059QF0k		5,55 (0)					
PHENOL (UNII: 339NCG							
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,						
Packaging							
# Item Code	Pa	ckage Description	Marketi	ing St	art Date	Ma	rketing End Date
1 NDC:36987-2299-1	5 mL in 1 V	/IAL, MULTI-DOSE					
2 NDC:36987-2299-2	10 mL in 1	VIAL, MULTI-DOSE					
3 NDC:36987-2299-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC:36987-2299-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Info	rmation						
•						_	
Marketing Category		on Number or Monograph	Citation	Mark	eting Start I	Jate	Marketing End Date
DIA							
	BLA102192			08/29/	1972		
CORN GRASS				08/29/	1972		
C ORN GRASS corn grass injection, s	solution			08/29/	1972		
CORN GRASS corn grass injection, s Product Informati	solution	HUMAN PRESCRIPTION DRU				rce)	NDC:36987-2307
CORN GRASS corn grass injection, s Product Informati Product Type	solution on	HUMAN PRESCRIPTION DRU	JG		1972 n Code (Sou	rce)	NDC:36987-2307
CORN GRASS corn grass injection, s Product Informati	solution on	HUMAN PRESCRIPTION DRU INTRADERMAL, SUBCUTAN	JG			rce)	NDC:36987-2307
CORN GRASS corn grass injection, s Product Informati Product Type	solution on		JG			rce)	NDC:36987-2307
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati	solution on	INTRADERMAL, SUBCUTAN	JG			rce)	NDC:36987-2307
BLA CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati	on Active Moi	INTRADERMAL, SUBCUTAN	JG		n Code (Sou		
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/	solution on Active Moi Ingre	INTRADERMAL, SUBCUTAN e ty e dient Name	JG NEOUS	Iter	n Code (Sou Basis of Str	rength	Strength
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/	solution on Active Moi Ingre	INTRADERMAL, SUBCUTAN	JG NEOUS	Iter	n Code (Sou	rength	
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/	solution on Active Moi Ingre	INTRADERMAL, SUBCUTAN e ty e dient Name	JG NEOUS	Iter	n Code (Sou Basis of Str	rength	Strength
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/ ZEA MAYS POLLEN (U	solution on on Active Moi Ingre NII: 74PD8J616	INTRADERMAL, SUBCUTAN e ty e dient Name	JG NEOUS	Iter	n Code (Sou Basis of Str	rength	Strength
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/	solution on on Active Moi Ingre NII: 74PD8J616	INTRADERMAL, SUBCUTAN e ty e dient Name	JG NEOUS	Iter	n Code (Sou Basis of Str	rength	Strength
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/ ZEA MAYS POLLEN (U	solution on on Active Moi Ingre NII: 74PD8J616	INTRADERMAL, SUBCUTAN e ty e dient Name	JG NEOUS	Iter	n Code (Sou Basis of Str	rength	Strength
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/ ZEA MAYS POLLEN (U	on on Active Moi Ingre NII: 74PD8J610	INTRADERMAL, SUBCUTAN ety edient Name 5H) (ZEA MAYS POLLEN - UN Ingredient Name	JG NEOUS	Iter	n Code (Sou Basis of Str	rength	Strength 40000 [PNU] in 1 m]
CORN GRASS corn grass injection, s Product Informati Product Type Route of Administrati Active Ingredient/ ZEA MAYS POLLEN (U Inactive Ingredien	solution on Active Moi Ingre NII: 74PD8J616 Its	INTRADERMAL, SUBCUTAN ety edient Name 5H) (ZEA MAYS POLLEN - UN Ingredient Name 8X)	JG NEOUS	Iter	n Code (Sou Basis of Str	rength	Strength 40000 [PNU] in 1 m]

PHENOL (UNII: 339NCG44TV)

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:36987-2307-1	5 mL in 1 VIAL, MULTI-DOSE				
2	NDC:36987-2307-2	10 mL in 1 VIAL, MULTI-DOSE				
3	NDC:36987-2307-3	30 mL in 1 VIAL, MULTI-DOSE				

Mar	keting Info	rmation						
Mark BLA	ceting Category	Application BLA102192	on Number or Monograph	Citation	Marke 08/29/1	e ting Start D 972	ate Ma	arketing End Dat
	J CH QUACI quack grass inj							
	luct Informatio	on			-	/-		
	uct T yp e		HUMAN PRESCRIPTION DR		lte m	Code (Sour	·ce)	NDC:36987-2315
Route	of Administration	on	INTRADERMAL, SUBCUTA	NEOUS				
Activ	e Ingredient//	Active Moi	ety					
		Ingr	edient Name			Basis of S	trength	Strength
	US REPENS POLI N2T85TA2O)	L EN (UNII: ON	2T85TA2O) (ELYMUS REPEN	NS POLLEN -	-	ELYMUS RE POLLEN	PENS	40000 [PNU] in 1 mL
Inact	ive Ingredien	ts						
			Ingredient Name					Strength
	UM CHLORIDE (U	-						
	JM BICARBONAT	•	5V39QO)					
	\mathbf{R} (UNII: 059QF0K							
PHEN	DL (UNII: 339NCG	441V)						
Pack	aging							
#	Item Code	Pac	kage Description	Market	ting Sta	art Date	Mark	eting End Date
	2:36987-2315-1		IAL, MULTI-DOSE					
	2:36987-2315-2		VIAL, MULTI-DOSE					
	C:36987-2315-3		VIAL, MULTI-DOSE					
4 NDC	2:36987-2315-4	50 mL in 1	VIAL, MULTI-DOSE					
		umation						
Mar	keting Info	rillation						
	keting Info teting Category		on Number or Monograph	Citation	Marke	eting Start D	ate Ma	arketing End Dat

I

GRAMA GRASS

grama grass injection, solution

Product Informati	on						
Product Type		HUMAN PRESCRIPTION DR	RUG	Ite m	Code (Sourc	e) NI	DC:36987-2325
Route of Administrati	on	INTRADERMAL, SUBCUTA	NEOUS				
Koute of Auministrati	UII						
Active Ingredient/	Active Moie	ty					
	Ingre	dient Name			Basis of S	trength	Strength
BOUTELOUA GRACILI POLLEN - UNII:2XO0831		NII: 2XO08315X1) (BOUTEL	LOUA GRACILIS	5	BOUTELOUA POLLEN	GRACILIS	40000 [PNU] in 1 mL
Inactive Ingredien	its						
		Ingredient Name					Strength
SODIUM CHLORIDE (U	JNII: 451W47IQ8						
SODIUM BICARBONAT							
WATER (UNII: 059QF0K	KOOR)						
PHENOL (UNII: 339NCG	G44TV)						
Packaging							
0 0							
00	Pac	kage Description	Marketin	ıg Sta	rt Date	Market	ing End Date
# Item Code		kage Description AL, MULTI-DOSE	Marketin	ıg Sta	art Date	Market	ing End Date
# Item Code 1 NDC:36987-2325-1	5 mL in 1 VI	• ·	Marketin	ıg Sta	nrt Date	Market	ing End Date
# Item Code 1 NDC:36987-2325-1 2 NDC:36987-2325-2	5 mL in 1 VI 10 mL in 1 V	AL, MULTI-DOSE	Marketin	ıg Sta	nrt Date	Market	ing End Date
 # Item Code 1 NDC:36987-2325-1 2 NDC:36987-2325-2 3 NDC:36987-2325-3 	5 mL in 1 VI 10 mL in 1 V 30 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE	Marketin	ıg Sta	nrt Date	Market	ing End Date
 # Item Code 1 NDC:36987-2325-1 2 NDC:36987-2325-2 3 NDC:36987-2325-3 	5 mL in 1 VI 10 mL in 1 V 30 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE /IAL, MULTI-DOSE	Marketin	ıg Sta	art Date	Market	ing End Date
# Item Code 1 NDC:36987-2325-1 2 NDC:36987-2325-2 3 NDC:36987-2325-3 4 NDC:36987-2325-4	5 mL in 1 VI 10 mL in 1 V 30 mL in 1 V 50 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE /IAL, MULTI-DOSE	Marketin	ıg Sta	art Date	Market	ing End Date
00	5 mL in 1 VI 10 mL in 1 V 30 mL in 1 V 50 mL in 1 V	IAL, MULTI-DOSE /IAL, MULTI-DOSE /IAL, MULTI-DOSE			nrt Date		ing End Date keting End Date

JOHNSON GRASS

johnson grass injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2333
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	40000 [PNU] in 1 mL
POLLEN - UNII:577VA5B4HP)	POLLEN	in 1 mL

Inactive Ingredie		Ingredient Name				Strength
SO DIUM CHLO RIDE	(UNII: 451W47IO)	-				Strength
SODIUM BICARBON						
WATER (UNII: 059QF		5 (55 Q (5)				
PHENOL (UNII: 339 N						
Packaging						
# Item Code	Pao	ckage Description	Market	ing Start Date	Mark	eting End Date
1 NDC:36987-2333-1		TAL, MULTI-DOSE		-		-
2 NDC:36987-2333-2	10 mL in 1	VIAL, MULTI-DOSE				
3 NDC:36987-2333-3	30 mL in 1	VIAL, MULTI-DOSE				
4 NDC:36987-2333-4	50 mL in 1	VIAL, MULTI-DOSE				
Marketing Inf	ormation					
Marketing Categor	y Applicatio	on Number or Monograph	n Citation	Marketing Start Dat	e Ma	rketing End Dat
BLA	BLA102192			08/29/1972		
CULTIVATEI						
Product Informa	tion					
Product Type						
		HUMAN PRESCRIPTION DE	RUG	Item Code (Source	e)	NDC:36987-2341
	ition			Item Code (Source	2)	NDC:36987-2341
Route of Administra	ition	HUMAN PRESCRIPTION DE		Item Code (Source	2)	NDC:36987-2341
	ıtion			Item Code (Source	2)	NDC:36987-2341
		INTRADERMAL, SUBCUTA		Item Code (Source	2)	NDC:36987-2341
Route of Administra	t/Active Moi	INTRADERMAL, SUBCUTA		Item Code (Source Basis of Stree		NDC:36987-2341 Strength
Route of Administra Active Ingredien AVENA SATIVA POL	t/Active Moi Ingre	INTRADERMAL, SUBCUTA	ANEOUS	Basis of Stre Avena Sativa	ength	Strength 40000 [PNU]
Route of Administra Active Ingredien Avena sativa Pol	t/Active Moi Ingre	INTRADERMAL, SUBCUTA ety edient Name	ANEOUS	Basis of Stre	ength	Strength
Route of Administra Active Ingredien Avena sativa Pol	t/Active Moi Ingre	INTRADERMAL, SUBCUTA ety edient Name	ANEOUS	Basis of Stre Avena Sativa	ength	Strength 40000 [PNU]
Route of Administra Active Ingredien AVENA SATIVA POL UNII:A7IKY24TR7)	t/Active Moi Ingro Len (UNII: A71K	INTRADERMAL, SUBCUTA ety edient Name	ANEOUS	Basis of Stre Avena Sativa	ength	Strength 40000 [PNU]
Route of Administra Active Ingredien AVENA SATIVA POL UNII:A7IKY24TR7)	t/Active Moi Ingro Len (UNII: A71K	INTRADERMAL, SUBCUTA ety edient Name Y24TR7) (AVENA SATIVA PO	ANEOUS	Basis of Stre Avena Sativa	ength	Strength 40000 [PNU] in 1 mL
Route of Administra Active Ingredien Avena sativa pol UNII:A7IKY24TR7) Inactive Ingredie	t/Active Moi Ingro LEN (UNII: A7IK ents	INTRADERMAL, SUBCUTA ety edient Name Y24TR7) (AVENA SATIVA PC Ingredient Name	ANEOUS	Basis of Stre Avena Sativa	ength	Strength 40000 [PNU]
Route of Administra Active Ingredien	t/Active Moi Ingro LEN (UNII: A7IK ents (UNII: 451W47IQ	INTRADERMAL, SUBCUTA ety edient Name Y24TR7) (AVENA SATIVA PO Ingredient Name 8X)	ANEOUS	Basis of Stre Avena Sativa	ength	Strength 40000 [PNU] in 1 mL

WATER (UNII: 059QF0KO0R)

PHENOL (UNII: 339NCG44TV)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36987-2341-1	5 mL in 1 VIAL, MULTI-DOSE		

	Marketing Category	Application Number or Monograph Citation BLA102192	08/29/1972				
N	Marketing Category	Application Number of Monograph Citation		~			
		Application Number or Managraph Citation	Marketing Start Date	Marketing End Date			
Marketing Information							
4	NDC:36987-2341-4	50 mL in 1 VIAL, MULTI-DOSE					
-	NDC:36987-2341-3 NDC:36987-2341-4	30 mL in 1 VIAL, MULTI-DOSE50 mL in 1 VIAL, MULTI-DOSE					

QUACK GRASS

quack grass injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2359
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ELYMUS REPENS POLLEN (UNII: ON2T85TA2O) (ELYMUS REPENS POLLEN - UNII:ON2T85TA2O)	ELYMUS REPENS POLLEN	40000 [PNU] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	NDC:36987-2359-1	5 mL in 1 VIAL, MULTI-DOSE		
2 N	NDC:36987-2359-2	10 mL in 1 VIAL, MULTI-DOSE		
3 N	NDC:36987-2359-3	30 mL in 1 VIAL, MULTI-DOSE		
4 N	NDC:36987-2359-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Info	Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
BLA	BLA102192	08/29/1972					

CULTIVATED RYE

Product Informatio	n						
Product T ype		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sourc	e) N	NDC:36987-2369
Route of Administratio	n	INTRADERMAL, SUBCUTA	NEOUS				
Active Ingredient/A	Active Moi	ety					
	Ingr	edient Name			Basis of St	rength	Strength
SECALE CEREALE POL UNII:16 KAZ8 AO1O)	LEN (UNII: 16	KAZ8AO1O) (SECALE CERE	ALE POLLEN		SECALE CERI POLLEN	EALE	40000 [PNU] in 1 mL
Inactive Ingredient	S						
		Ingredient Name					Strength
SODIUM CHLORIDE (UI	NII: 451W47IQ	BX)					
SO DIUM BICARBONAT	E (UNII: 8 MDF	5V39QO)					
PHENOL (UNII: 339NCG4	44TV)						
WATER (UNII: 059QF0K							
	OOR)						
Packaging		alogo Deseriation	Mayleet	ing Sta	at Data	Marka	ting End Data
Packaging # Item Code	Pa	ckage Description	Market	ing Sta	rt Date	Marke	eting End Date
Packaging#Item CodeINDC:36987-2369-1	Pa 5 mL in 1 V	/IAL, MULTI-DOSE	Market	ing Sta	rt Date	Marke	ting End Date
Fackaging Item Code NDC:36987-2369-1 NDC:36987-2369-2	Pa 5 mL in 1 V 10 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	rt Date	Marke	eting End Date
Packaging # Item Code 1 NDC:36987-2369-1 2 NDC:36987-2369-2 3 NDC:36987-2369-3	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	rt Date	Marke	ting End Date
Packaging # Item Code 1 NDC:36987-2369-1 2 NDC:36987-2369-2 3 NDC:36987-2369-3	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	rt Date	Marke	ting End Date
Packaging Item Code I NDC:36987-2369-1 I NDC:36987-2369-2 I NDC:36987-2369-3 I NDC:36987-2369-3	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	rt Date	Marke	ting End Date
Item Code Item Code I NDC:36987-2369-1 I NDC:36987-2369-2 I NDC:36987-2369-3 I NDC:36987-2369-3	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			rt Date		ting End Date Reting End Dat
Packaging Item Code I NDC:36987-2369-1 I NDC:36987-2369-2 I NDC:36987-2369-3 I NDC:36987-2369-3 I NDC:36987-2369-1	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation		ting Start Da		
Packaging Item Code I NDC:36987-2369-1 I NDC:36987-2369-2 I NDC:36987-2369-3 I NDC:36987-2369-3 I NDC:36987-2369-3	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Application	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start Da		
Packaging I Item Code 1 NDC:36987-2369-1 2 NDC:36987-2369-2 3 NDC:36987-2369-3 4 NDC:36987-2369-4	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Application	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start Da		
Packaging I Item Code 1 NDC:36987-2369-1 2 NDC:36987-2369-2 3 NDC:36987-2369-3 4 NDC:36987-2369-4 Marketing Information Marketing Category BLA	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Example Application BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start Da		
Packaging I Item Code 1 NDC:36987-2369-1 2 NDC:36987-2369-2 3 NDC:36987-2369-3 4 NDC:36987-2369-3 MDC:36987-2369-4	Pa 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Hard Station Application BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start Da		
Packaging I Item Code NDC:36987-2369-1 NDC:36987-2369-2 NDC:36987-2369-3 NDC:36987-2369-3 NDC:36987-2369-4 NDC:36987-2369-4 NDC:36987-2369-4 Marketing Information Marketing Category BLA GIANT WILD R Giant wild rye injection	S mL in 1 S mL in 1 30 mL in 1 30 mL in 1 50 mL in 1 SO mL in 1 Main mL in 1 SO mL in 1 SO mL in 1 Main mL in 1 SO mL in 1 Main mL in 1 Main mL in 1 SO mL in 1 Main mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start Da		
Packaging Item Code NDC:36987-2369-1 NDC:36987-2369-2 NDC:36987-2369-3 NDC:36987-2369-3 NDC:36987-2369-4	S mL in 1 S mL in 1 30 mL in 1 30 mL in 1 50 mL in 1 SO mL in 1 Main mL in 1 SO mL in 1 SO mL in 1 Main mL in 1 SO mL in 1 Main mL in 1 Main mL in 1 SO mL in 1 Main mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke 08/29/19	ting Start Da	ite Mai	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LEYMUS CONDENSATUS POLLEN (UNII: 257GC6Q00Q) (LEYMUS CONDENSATUS POLLEN - UNII:257GC6Q00Q)	LEYMUS CONDENSATUS POLLEN	40000 [PNU] in 1 mL

Ina	ctive Ingredients	6		
		Strength		
soi	DIUM CHLORIDE (UN	II: 451W47IQ8X)		
soi	DIUM BICARBONATE	E (UNII: 8MDF5V39QO)		
PHE	NOL (UNII: 339NCG4	4TV)		
WA'	TER (UNII: 059QF0KC	00B)		
Pa	ckaging Item Code	Package Description	Marketing Start Date	Marketing End Date
Pao #	ckaging		Marketing Start Date	Marketing End Date

Marketing Information						
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
A102192	08/29/1972					
١	pplication Number or Monograph Citation	pplication Number or Monograph Citation Marketing Start Date				

30 mL in 1 VIAL, MULTI-DOSE

50 mL in 1 VIAL, MULTI-DOSE

3 NDC:36987-2377-3

4 NDC:36987-2377-4

ITALIAN RYE GRASS					
italian rye grass injection, solution					
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Ite m	Code (Source)	NDC:36	5987-2385
Route of Administration	INTRADERMAL, SUBCUTANEOUS				
Active Ingredient/Active Med	a 4				
Active Ingredient/Active Moi	•		Desis of Street	~ 4 h	C aver a sh
	r <mark>edient Name</mark> RUM POLLEN (UNII: VJI0WKK736) (LOLIU	TN A	Basis of Stren	-	Strength 40000 [PNU
PERENNE SSP. MULTIFLORUM POLLE		IVI	MULTIFLORUM POLI		in 1 mL
Inactive Ingredients					
macuve ingretients	In and in the Norma			C 4	+ h
	Ingredient Name			Str	ength
SO DIUM CHLORIDE (UNII: 451W47IQ SO DIUM BICARBONATE (UNII: 8 MDI	,				
PHENOL (UNII: 339NCG44TV)					
WATER (UNII: 059QF0K00R)					
Packaging					

# Item Code	Pa	ckage Description	Marke	ting Sta	rt Date	Ma	rketing En	d Date
1 NDC:36987-2385-1	5 mL in 1 V	/IAL, MULTI-DOSE						
2 NDC:36987-2385-2	10 mL in 1	VIAL, MULTI-DOSE						
3 NDC:36987-2385-3	30 mL in 1	VIAL, MULTI-DOSE						
4 NDC:36987-2385-4	50 mL in 1	VIAL, MULTI-DOSE						
Marketing Info	ormation							
Marketing Category	Applicatio	on Number or Monograp	h Citation	Marke	ting Start D	Date 1	Marketing	End Date
BLA	BLA102192			08/29/19	972			
SALT GRASS								
alt grass injection, s	olution							
Product Informat	ion							
			DUC	т.	Code (C		NDC/200	07 0005
Product T ype		HUMAN PRESCRIPTION D		Ite m	Code (Sou	rce)	NDC:369	57-2395
Route of Administrat		INTRADERMAL, SUBCUT						
Active Ingredient	Active Moi	ety						
Active Ingredient	Ingr	redient Name			Basis of	Streng	gth St	rength
J	Ingr	5	IS SPICATA P	OLLEN	Basis of DISTICHLIS POLLEN	-) [PNU]
DISTICHLIS SPICATA - UNII:GOA51670YV)	Ing r POLLEN (UNI	redient Name	IS SPICATA P	OLLEN	DISTICHLIS	-	A 4000) [PNU]
DISTICHLIS SPICATA - UNII:GOA51670YV)	Ing r POLLEN (UNI	redient Name	IS SPICATA P	POLLEN	DISTICHLIS	-	A 4000	D [PNU] hL
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredie	Ingr POLLEN (UNI nts	redient Name : GOA51670 YV) (DISTICHL Ingredient Name	IS SPICATA P	OLLEN	DISTICHLIS	-	CA 4000 in 1 n	D [PNU] hL
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredie SODIUM CHLORIDE (1	Ingr POLLEN (UNII nts UNII: 451W47IQ	redient Name :: GOA51670 YV) (DISTICHL Ingredient Name 8X)	IS SPICATA P	POLLEN	DISTICHLIS	-	CA 4000 in 1 n	D [PNU] hL
DISTICHLIS SPICATA	Ing r POLLEN (UNII nts UNII: 451W47IQ3 TE (UNII: 8 MDF	redient Name :: GOA51670 YV) (DISTICHL Ingredient Name 8X)	IS SPICATA P	POLLEN	DISTICHLIS	-	CA 4000 in 1 n	D [PNU] hL
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredie SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC)	Ing r POLLEN (UNII nts UNII: 451W47IQ TE (UNII: 8 MDF G44TV)	redient Name :: GOA51670 YV) (DISTICHL Ingredient Name 8X)	IS SPICATA P	POLLEN	DISTICHLIS	-	CA 4000 in 1 n	D [PNU] hL
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredie SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC)	Ing r POLLEN (UNII nts UNII: 451W47IQ TE (UNII: 8 MDF G44TV)	redient Name :: GOA51670 YV) (DISTICHL Ingredient Name 8X)	IS SPICATA P	POLLEN	DISTICHLIS	-	CA 4000 in 1 n	D [PNU] hL
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredie SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC) WATER (UNII: 059QF0)	Ing r POLLEN (UNII nts UNII: 451W47IQ TE (UNII: 8 MDF G44TV)	redient Name :: GOA51670 YV) (DISTICHL Ingredient Name 8X)	IS SPICATA P	POLLEN	DISTICHLIS	-	CA 4000 in 1 n	D [PNU] hL
DISTICHLIS SPICATA UNII:GOA51670 YV) Inactive Ingredien SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC) WATER (UNII: 059QF) Packaging	Ing r POLLEN (UNII nts UNII: 451W47IQ: TE (UNII: 8 MDF G44TV) KO0R)	redient Name :: GOA51670 YV) (DISTICHL Ingredient Name 8X)			DISTICHLIS	SPICAT	CA 4000 in 1 n	0 [PNU] 1L
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredien SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC) WATER (UNII: 059QF0) Packaging # Item Code	Ing r POLLEN (UNII nts UNII: 451W47IQ4 TE (UNII: 8 MDF G44TV) KO0R)	redient Name : GOA51670 YV) (DISTICHL Ingredient Name 8X) 75V39QO)			DISTICHLIS POLLEN	SPICAT	A 4000 in 1 n Stren	o [PNU] aL
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredien SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC) WATER (UNII: 059QF0) Packaging # Item Code 1 NDC:36987-2395-1	Ing r POLLEN (UNII nts UNII: 451W47IQ3 TE (UNII: 8 MDF G44TV) KO0 R) B44TV KO0 R) Fat 1 V	redient Name : GOA51670 YV) (DISTICHL Ingredient Name 8X) 75V39QO) Ckage Description			DISTICHLIS POLLEN	SPICAT	A 4000 in 1 n Stren	0 [PNU] 1L
DISTICHLIS SPICATA UNII:GOA51670 YV) Inactive Ingredien SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC) WATER (UNII: 059QF0) Packaging I tem Code NDC:36987-2395-1 NDC:36987-2395-2	Ing r POLLEN (UNII nts	redient Name : GOA51670YV) (DISTICHL Ingredient Name 8X) 75V39QO) Ckage Description VIAL, MULTI-DOSE			DISTICHLIS POLLEN	SPICAT	A 4000 in 1 n Stren	0 [PNU] 1L
DISTICHLIS SPICATA - UNII:GOA51670YV) Inactive Ingredien SODIUM CHLORIDE (1 SODIUM BICARBONA PHENOL (UNII: 339NC) WATER (UNII: 059QF0) Packaging	Ingr POLLEN (UNII nts UNI: 451W47IQ3 TE (UNII: 8MDF G44TV) KOUR SmL in 1% 10 mL in 1 30 mL in 1	redient Name : GOA51670YV) (DISTICHL Ingredient Name 8X) 75V39QO) 75V39QO) Ckage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE			DISTICHLIS POLLEN	SPICAT	A 4000 in 1 n Stren	0 [PNU] 1L
DISTICHLIS SPICATA - UNII:GOA51670 YV) Inactive Ingredien SODIUM CHLORIDE (I SODIUM BICARBONA PHENOL (UNII: 339 NCC) WATER (UNII: 059 QF0) # Item Code 1 NDC:36987-2395-1 2 NDC:36987-2395-2 3 NDC:36987-2395-3 4 NDC:36987-2395-4	Ingr POLLEN (UNII POLLEN (UNII Ingr Ingr							

	SS						
velvet grass injection,	, solution						
Product Informati	on						
Product Type		HUMAN PRESCRIPTION DR	UG	Itom	Code (Soui	(a)	NDC:36987-240
				ite iii		(e)	NDC.30307-240
Route of Administration	ion	INTRADERMAL, SUBCUTA	NEOUS				
Active Ingredient/	Active Moi	ety					
0		edient Name			Basis of	Strengt	h Strengt
DISTICHLIS SPICATA - UNII:GOA51670 YV)	POLLEN (UNI	: GOA51670YV) (DISTICHLIS	S PICATA PO	LLEN	DISTICHLIS POLLEN	SPICATA	
Inactive Ingredien	nts						
5		Ingredient Name					Strength
SODIUM CHLORIDE (U	JNII: 451W47IQ	•					0
SO DIUM BICARBO NAT	FE (UNII: 8 MDF	5V39QO)					
PHENOL (UNII: 339 NCC	G44TV)						
WATER (UNII: 059QF0F	KO0R)						
Packaging							
	Pac	ckage Description	Marketi	ng Sta	rt Date	Marl	keting End Dat
# Item Code		t kage Description TAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Marl	keting End Dat
# Item Code 1 NDC:36987-2407-1	5 mL in 1 V	• ·	Marketi	ng Sta	rt Date	Marl	keting End Dat
# Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2	5 mL in 1 V 10 mL in 1	IAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Marl	keting End Dat
Packaging # Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Marl	keting End Dat
# Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Marl	keting End Dat
 # Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4 	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE					
Item Code NDC:36987-2407-1 NDC:36987-2407-2 NDC:36987-2407-3 NDC:36987-2407-3 NDC:36987-2407-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start D		keting End Dat larketing End D
Item Code NDC:36987-2407-1 NDC:36987-2407-2 NDC:36987-2407-3 NDC:36987-2407-3 NDC:36987-2407-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation		ting Start D		
# Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4 Warketing Info Marketing Category BLA	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Application BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start D		
# Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4 Warketing Info Marketing Category BLA CULTIVATED	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 4000000000000000000000000000000000000	TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start D		
# Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4 Warketing Info Marketing Category BLA CULTIVATED	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 4000000000000000000000000000000000000	TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start D		
# Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 rmation Application BLA102192	TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start D		
 # Item Code 1 NDC:36987-2407-1 2 NDC:36987-2407-2 3 NDC:36987-2407-3 4 NDC:36987-2407-4 Marketing Info Marketing Category BLA CULTIVATED cultivated wheat injec	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 rmation Application BLA102192	TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation (Marke)8/29/19	ting Start D)ate M	

Active Ingredient/Active Moiety
Ingredient Name Basis of Strength Strength

	:F1KAH8374D)	POLLEN (UNII: F1KAH8374D) (TRITICUM A		POLLEN		40000 [PNU] in 1 mL
Inact	tive Ingredien	ts				
		Ingredient Name				Strength
SODI	UM CHLORIDE (U	NII: 451W47IQ8X)				
SODI	UM BICARBONAT	E (UNII: 8MDF5V39QO)				
PHEN	OL (UNII: 339 NCG	44TV)				
WATE	E R (UNII: 059QF0K	O0R)				
Pack	aging					
	aging Item Code	Package Description	Marketing S	tart Date	Marke	ting End Date
#	0 0	Package Description 5 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Marke	ting End Date
# 1 ND0	Item Code	Ŭ Î	Marketing S	tart Date	Marke	ting End Date
#1 NDC2 NDC	Item Code C:36987-2415-1	5 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Marke	ting End Date
 # 1 ND0 2 ND0 3 ND0 	Item Code C:36987-2415-1 C:36987-2415-2	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Marke	ting End Date
 # 1 ND0 2 ND0 3 ND0 	Item Code C:36987-2415-1 C:36987-2415-2 C:36987-2415-3	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Marke	ting End Date
 # 1 ND0 2 ND0 3 ND0 	Item Code C:36987-2415-1 C:36987-2415-2 C:36987-2415-3	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Marke	ting End Date
 # ND0 ND0 ND0 ND0 ND0 	Item Code C:36987-2415-1 C:36987-2415-2 C:36987-2415-3 C:36987-2415-4	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE 50 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Marke	ting End Date
 # ND0 ND0 ND0 ND0 	Item Code C:36987-2415-1 C:36987-2415-2 C:36987-2415-3 C:36987-2415-4	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE 50 mL in 1 VIAL, MULTI-DOSE				
 # ND0 ND0 ND0 ND0 	Item Code C:36987-2415-1 C:36987-2415-2 C:36987-2415-3 C:36987-2415-4	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE 50 mL in 1 VIAL, MULTI-DOSE		se ting Start Date		ting End Date •keting End Dat

WEST WHEAT GRASS	5				
west wheat grass injection, solut	ion				
Product Information					
Product T ype	HUMAN PRESCRIPTION DRUG	Ite m	Code (Source)	NE	C:36987-2423
Route of Administration	INTRADERMAL, SUBCUTANEOUS				
Active Ingredient/Active M	oiety				
In	gredient Name		Basis of Stren	gth	Strength
PASCOPYRUM SMITHII POLLEN (POLLEN - UNII:6 AU0 ZD8 T10)	UNII: 6 AU0 ZD8 T1O) (PASCO PYRUM SMITHII		PASCOPYRUM SMI POLLEN	THII	40000 [PNU] in 1 mL
Inactive Ingredients					
	Ingredient Name				Strength
SODIUM CHLORIDE (UNII: 451W47	IQ8X)				
SODIUM BICARBONATE (UNII: 8M	DF5V39QO)				
PHENOL (UNII: 339NCG44TV)					
WATER (UNII: 059QF0KO0R)					

Packaging								
#	Item Code	Package Description	Marke	ting Start Date	Marketing End Date			
1 N	DC:36987-2423-1	5 mL in 1 VIAL, MULTI-DOSE						
2 N	DC:36987-2423-2	10 mL in 1 VIAL, MULTI-DOSE						
3 N	DC:36987-2423-3	30 mL in 1 VIAL, MULTI-DOSE						
4 N	DC:36987-2423-4	50 mL in 1 VIAL, MULTI-DOSE						
Marketing Information								
Ma	rketing Category	Application Number or Monograph	Citation	Marketing Start Date	Marketing End Date			
BLA	B	3LA102192		08/29/1972				

	ection, solutio	11						
Product Informa	tion							
Product T ype	uct Type HUMAN PRESCRIPTION DRUG Item Code (Source)					ce) I	NDC:36987-2433	
Route of Administra	ntion	INTRADERMAL, SUBCUT	ANEOUS					
Active Ingredien	t/Active Moi	ety						
	Ingr	edient Name			Basis of S	Strength	Strength	
BROMUS INERMIS POLLEN (UNII: 766QT72BK6) (BROMUS INERMIS POLLEN - UNII:766QT72BK6) POLLEN					-	40000 [PNU] in 1 mL		
Inactive Ingredie	ents	Ingue dieut Nome					Strongth	
Ingredient Name SODIUM CHLORIDE (UNII: 451W47IQ8X)							Strength	
SODIUM BICARBON								
PHENOL (UNII: 339NO		. ,						
WATER (UNII: 059QF	0KO0R)							
Packaging								
# Item Code	Pac	kage Description	Marketir	Marketing Start Date		Marketing End Da		
		IAL, MULTI-DOSE					_	
1 NDC:36987-2433-1	10 mL in 1	VIAL, MULTI-DOSE						
		VIAL, MULTI-DOSE						
2 NDC:36987-2433-2	30 mL in 1							
2 NDC:36987-2433-2		VIAL, MULTI-DOSE						
 NDC:36987-2433-1 NDC:36987-2433-2 NDC:36987-2433-3 NDC:36987-2433-4 MDC:36987-2433-4 	50 mL in 1	VIAL, MULTI-DOSE						

08/29/1972

SMOOTH BI smooth brome inj							
Product Inform	action						
Product Type	lativii	HUMAN PRESCRIPTION DR	ШG	Ite m	Code (Sour	(CP)	NDC:36987-2441
Route of Adminis	tration	INTRADERMAL, SUBCUTA		ite in		,	
		,					
Active Ingredi	ent/Active Moi	ety					
	Ingi	redient Name			Basis of S	trength	Strength
BROMUS INERMIS UNII:766QT72BK6)	POLLEN (UNII: 70	56QT72BK6) (BROMUS INEF	GQT72BK6) (BROMUS INERMIS POLLEN -		BROMUS INERMIS POLLEN		40000 [PNU] in 1 mL
Inactive Ingred	lients						
macuve mgree	iie iits	Ingredient Name					Strength
SODIUM CHLORII		ottengti					
SODIUM BICARBO							
PHENOL (UNII: 339		. ,					
WATER (UNII: 0590	QF0KO0R)						
Packaging							
# Item Cod		ckage Description	Marketing Start Date M		Mark	Marketing End Date	
1 NDC:36987-2441		'IAL, MULTI-DOSE					
2 NDC:36987-2441		VIAL, MULTI-DOSE					
3 NDC:36987-2441		VIAL, MULTI-DOSE					
4 NDC:36987-2441	-4 50 mL in 1	VIAL, MULTI-DOSE					
Marketing I	nformation						
Marketing Categ		on Number or Monograph	Citation N	Marke	ting Start D	ate M	arketing End Dat
marketing Gateg	ory Applicau	on manufer of monograph			U	ute IVI	ar keeing End Dat
BLA	BLA102192		30	8/29/19	972		

Labeler - Nelco Laboratories, Inc. (054980867)

Registrant - Nelco Laboratories, Inc. (054980867)

Establishment							
Name	Address	ID/FEI	Business Operations				
Nelco Laboratories, Inc.		054980867	manufacture				

Revised: 12/2009