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.

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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)	NDC:36	987-2262
Route of Administration	INTRADERMAL, SUBCUTANEOUS	Ite III	cour (source)	1120.00	
Noute of Administration	INTRIDERVIL, SOBOUTANEOUS				
Active Ingredient/Active Moi	ety				
Ing	redient Name		Basis of Strengt	h	Strength
PASPALUM NOTATUM POLLEN (UM POLLEN - UNII:V003SHB7VK)	III: V003SHB7VK) (PASPALUM NOTATUM		PASPALUM NOTATU POLLEN		000 [PNU] 1 mL
Inactive Ingredients					
	Ingredient Name			Str	ength
	-				

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

De else else

Р	Packaging									
#	Item Code	Package Description	Marke	ting Start Date N	Marketing End Date					
1	NDC:36987-2262-1	5 mL in 1 VIAL, MULTI-DOSE								
2	NDC:36987-2262-2	10 mL in 1 VIAL, MULTI-DOSE								
3	NDC:36987-2262-3	30 mL in 1 VIAL, MULTI-DOSE								
4	NDC:36987-2262-4	50 mL in 1 VIAL, MULTI-DOSE								
N	Iarketing Inform	mation								
N	Marketing Category	Application Number or Monograph	Citation	Marketing Start Date	Marketing End Date					

Marketing Category	Application Number of Monograph Citation	Markeung Start Date	Marketing End Date	l
BLA	BLA102192	08/29/1972		l
				4

ANNUAL BLUE GRASS annual blue grass injection, solution **Product Information** HUMAN PRESCRIPTION DRUG NDC:36987-2271 **Product Type** Item Code (Source) **Route of Administration** INTRADERMAL, SUBCUTANEOUS **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength POA ANNUA POLLEN (UNII: 7U437HHU5C) (POA ANNUA POLLEN -POA ANNUA 10000 [PNU] UNII:7U437HHU5C) POLLEN in 1 mL

Strength

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2271-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2271-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2271-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2271-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Info	rmation						
Marketing Category		on Number or Monograph	Citation	Marke	ting Start Dat	e Ma	rketing End Da
BLA	BLA102192			08/29/19	72		
CANADIAN BL	UE GRAS	SS					
canadian blue grass ir	ijection, solu	tion					
Product Informati	on						
Product Type		HUMAN PRESCRIPTION DR	RUG	Ite m	Code (Source) [NDC:36987-2279
Route of Administrati	on	INTRADERMAL, SUBCUTA	NEOUS				
A -41	A						
Active Ingredient/		5			Pacie of Str	ongth	Strongth
PO A COMPRESSA POI	0	edient Name HCQ1NYV5) (POA COMPRES	SSA POLLEN	_	Basis of Str POA COMPRES	-	Strength 10000 [PNU]
UNII:50 HCQ1NYV5)			JUNIOLLEI		POLLEN	571	in 1 mL
Inactive Ingredien	its						
		Ingredient Name					Strength
SO DIUM CHLO RIDE (U	JNII: 451W47IQ8	3X)					Strength
SODIUM CHLORIDE (U SODIUM BICARBONAT	JNII: 451W47IQ8 FE (UNII: 8MDF	3X)					Strength
SODIUM CHLORIDE (U SODIUM BICARBONAT WATER (UNII: 059QF0F	JNII: 451W47IQ8 FE (UNII: 8 MDF (00 R)	3X)					Strength
SODIUM CHLORIDE (U SODIUM BICARBONAT WATER (UNII: 059QF0F	JNII: 451W47IQ8 FE (UNII: 8 MDF (00 R)	3X)					Strength
SODIUM CHLORIDE (U SODIUM BICARBONAT WATER (UNII: 059QF0F	JNII: 451W47IQ8 FE (UNII: 8 MDF (00 R)	3X)					Strength
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SODIUM CHLORIDE (U SODIUM BICARBONAT WATER (UNII: 059QF0F PHENOL (UNII: 339NCC Packaging # Item Code	JNII: 451W47IQ8 FE (UNII: 8 MDF (00 R) G44TV) Pac	3X) 5V39QO)	Market	ing Sta	ırt Date	Marke	
SODIUM CHLORIDE (U SODIUM BICARBONAT WATER (UNII: 059QF0F PHENOL (UNII: 339NCC PHENOL (UNII: 339NCC PHENOL (UNII: 339NCC I trem Code NDC:36987-2279-1	JNII: 451W47IQ8 FE (UNII: 8 MDF (00 R) G44TV) G44TV 5 mL in 1 V	3X) 5V39QO) ckage Description	Market	ing Sta	rt Date	Marke	
SO DIUM CHLO RIDE (U SO DIUM BICARBONAT WATER (UNII: 059QF0F PHENOL (UNII: 339NCC PHENOL (UNII: 339NCC PHENOL (UNII: 339NCC 1 NDC:36987-2279-1 NDC:36987-2279-2	UNII: 451W47IQ8 FE (UNII: 8 MDF 600 R) 644TV) 644TV 65 mL in 1 V 10 mL in 1	3X) 5V39QO) ckage Description TAL, MULTI-DOSE	Market	ing Sta	art Date	Marke	
SO DIUM CHLO RIDE (U SO DIUM BICARBONAT WATER (UNII: 059QF0F PHENOL (UNII: 339NCC	JNII: 451W47IQ8 FE (UNII: 8 MDF 300 R) 344TV) 344TV) 5 mL in 1 V 10 mL in 1 30 mL in 1	3X) 5V39QO) c kage Description /IAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	Irt Date	Marke	
SO DIUM CHLO RIDE (U SO DIUM BICARBONAT WATER (UNII: 059QF0F PHENOL (UNII: 339NCC	JNII: 451W47IQ8 FE (UNII: 8 MDF 300 R) 344TV) 344TV) 5 mL in 1 V 10 mL in 1 30 mL in 1	SX) SV39QO) SV39QO) Ckage Description TIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	Int Date	Marke	
SO DIUM CHLO RIDE (U SO DIUM BICARBONAT WATER (UNII: 059QF0F PHENOL (UNII: 339NCC	JNII: 451W47IQ8 FE (UNII: 8 MDF 300 R) 344TV) 344TV) 5 mL in 1 V 10 mL in 1 30 mL in 1	SX) SV39QO) SV39QO) Ckage Description TIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	Irt Date	Marke	
SODIUM CHLORIDE (U SODIUM BICARBONAT WATER (UNII: 059QF0F PHENOL (UNII: 339NCC	JNII: 451W47IQ8 FE (UNII: 8 MDF GOOR) G44TV) G44TV) G44TV G47TQ G44TV G47TQ G44TV G47TQ G47TQ G47TQ G47TVV G47TVV G47TVV G47TV	SX) SV39QO) SV39QO) Stage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Market	ing Sta	Int Date	Marke	
Inactive Ingredien South Chloride (U South BicArbonard Watter (UNII: 059QF04) PHENOL (UNII: 339NCC) PHENOL (UNII: 339NC) PHENOL (UNII: 339NC) <td>UNII: 451W47IQ8 FE (UNII: 8 MDF CO R) G44TV) G44TV G 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1</td> <td>SX) SV39QO) SV39QO) Stage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE</td> <td></td> <td></td> <td>art Date</td> <td></td> <td></td>	UNII: 451W47IQ8 FE (UNII: 8 MDF CO R) G44TV) G44TV G 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	SX) SV39QO) SV39QO) Stage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			art Date		

brome grass injection, solution

Product Information

		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Source) NI	DC:36987-2287
Route of Administration	n	INTRADERMAL, SUBCUTA	NEOUS				
Active Ingredient/A							
	•	edient Name			Basis of Str	-	Strength
BROMUS INERMIS POLI UNII:766QT72BK6)	L EN (UNII: 76	6QT72BK6) (BROMUS INER	MIS POLLEN -		BROMUS INER POLLEN	MIS	10000 [PNU] in 1 mL
Inactive Ingredients	5						
	-	Ingredient Name					Strength
SODIUM CHLORIDE (UN	III: 451W47IQ	-					0
SODIUM BICARBONATE	E (UNII: 8 MDF	5V39QO)					
WATER (UNII: 059QF0KC	00R)						
PHENOL (UNII: 339NCG4	4TV)						
Packaging							
# Item Code	Pa	kage Description	Marketin	g Sta	rt Date	Market	ing End Date
1 NDC:36987-2287-1	5 mL in 1 V	YIAL, MULTI-DOSE					
2 NDC:36987-2287-2	10 mL in 1	VIAL, MULTI-DOSE					
3 NDC:36987-2287-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC:36987-2287-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Infor	mation						
0		on Number or Monograph	Citation M	/Jarke	ting Start Date	e Mar	keting End Da
Marketing Category		on Number or Monograph		/larke 3/29/19	-	e Mar	keting End Da
Marketing Category	Applicatio	on Number or Monograph			-	e Mar	keting End Da
Marketing Category BLA	Applicatio BLA102192	on Number or Monograph			-	e Mar	keting End Da
Marketing Category BLA	Applicatio BLA102192 S	on Number or Monograph			-	e Mar	keting End Da
	Applicatio BLA102192 S	on Number or Monograph			-	e Mar	keting End Da
Marketing Category BLA	Applicatio BLA102192 S Solution	on Number or Monograph			-	e Mar	keting End Da
Marketing Category BLA	Applicatio BLA102192 S Solution	on Number or Monograph	30	3/29/19	-		
Marketing Category BLA	Applicatio BLA102192 S solution		UG	3/29/19)72		
Marketing Category BLA	Applicatio BLA102192 S solution n	HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAI	UG	3/29/19)72		
Marketing Category BLA I CANARY GRASS canary grass injection, Product Information Product Type	Application BLA102192 S solution n n	HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAN	UG	3/29/19	Code (Source) NI	DC:36987-2295
Marketing Category BLA I CANARY GRASS canary grass injection, Product Information Product Type Route of Administration Active Ingredient/A	Applicatio BLA102192 S solution n n sctive Moie Ingr	HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAI	UG NEOUS	3/29/19	Code (Source Basis of St) NI	DC:36987-2295

Inactive Ingredients

			Ingredient Name				Strength
SOD	IUM CHLORIDE (U	NII: 451W47IQ	3X)				
SOD	IUM BICARBONAT	'E (UNII: 8 MDF	5V39QO)				
WAT	ER (UNII: 059QF0K	.00R)					
PHEN	NOL (UNII: 339NCG	44TV)					
Pac	kaging						
#	Item Code	Pa	ckage Description	Marketing	g Start Date	Mai	keting End Date
1 ND	C:36987-2295-1	5 mL in 1 V	IAL, MULTI-DOSE				
2 ND	OC:36987-2295-2	10 mL in 1	VIAL, MULTI-DOSE				
3 ND	C:36987-2295-3	30 mL in 1	VIAL, MULTI-DOSE				
4 ND	C:36987-2295-4	50 mL in 1	VIAL, MULTI-DOSE				
Ma	rketing Info	rmation					
Mar	keting Category	Applicatio	on Number or Monograph	Citation M	arketing Start D	ate N	Aarketing End Date
BLA	0 0 0	BLA102192	0		29/1972		U
COI	RN GRASS						
		abition					
20111	grass injection, s	01001011					
_							
Pro	duct Informatio	on					
Proc	luct Type		HUMAN PRESCRIPTION DR	UG 1	ltem Code (Sour	ce)	NDC:36987-2303
Rout	te of Administration	on	INTRADERMAL, SUBCUTA	NEOUS			
Acti	ve Ingredient/A	Active Moi	ety				
		Ingr	edient Name		Basis of Str	ength	Strength
						_	_
ZEA	MAYS POLLEN (U	NII: 74PD8J616	6H) (ZEA MAYS POLLEN - UN	NII:74PD8J616H)	ZEA MAYS PO	DLLEN	10000 [PNU] in 1 mI
ZEA	MAYS POLLEN (U	NII: 74PD8J616	5H) (ZEA MAYS POLLEN - UN	NII:74PD8J616H)	ZEA MAYS PC	OLLEN	10000 [PNU] in 1 ml
ZEA	MAYS POLLEN (UI	NII: 74PD8J616	5H) (ZEA MAYS POLLEN - UN	NII:74PD8 J6 16 H)	ZEA MAYS PC	DLLEN	10000 [PNU] in 1 m]
	MAYS POLLEN (U		5H) (ZEA MAYS POLLEN - UN	NII:74PD8J616H)	ZEA MAYS PC	DLLEN	10000 [PNU] in 1 m

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

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36987-2303-1	5 mL in 1 VIAL, MULTI-DOSE		
2 NDC:36987-2303-2	10 mL in 1 VIAL, MULTI-DOSE		
3 NDC:36987-2303-3	30 mL in 1 VIAL, MULTI-DOSE		

	rketing Info	rmation						
Mar	keting Category	Applicatio	on Number or Monograph	Citation	Marke	ting Start D	ate Ma	rketing End Dat
BLA		BLA102192		C	08/29/19	72		
C O I	UCH QUACH	K GRASS	5					
couc	h quack grass inje	ection, solut	ion					
Pro	duct Informatio	on						
Proc	luct T ype		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sour	ce)	NDC:36987-2311
	te of Administratio	on	INTRADERMAL, SUBCUTA	NEOUS				
Acti	ve Ingredient/A	Active Moi	ety					
			redient Name			Basis of S	trength	Strength
		L EN (UNII: ON	2T85TA2O) (ELYMUS REPEN	NS POLLEN -		ELYMUS RE POLLEN	PENS	10000 [PNU] in 1 mL
UNII.	ON2T85TA2O)					POLLEN		III I IIIL
Inac	tive Ingredient	ts						
			Ingredient Name					Strength
	IUM CHLORIDE (U							
	IUM BICARBONAT	•	5V39QO)					
	ER (UNII: 059QF0K)							
PHE	OL (ONII. 339NCG	441 V)						
Pac	kaging							
#	Item Code	Pac	kage Description	Marketi	ng Sta	rt Date	Mark	eting End Date
	DC:36987-2311-1		IAL, MULTI-DOSE		U			U
1 NE	DC:36987-2311-2	10 mL in 1	VIAL, MULTI-DOSE					
		30 mL in 1	VIAL, MULTI-DOSE					
2 NE	DC:36987-2311-3							
2 NE3 NE	DC:36987-2311-3 DC:36987-2311-4	50 mL in 1	VIAL, MULTI-DOSE					
2 NE3 NE		50 mL in 1	VIAL, MULTI-DOSE					
 2 NE 3 NE 4 NE 			VIAL, MULTI-DOSE					
 2 NE 3 NE 4 NE 	DC:36987-2311-4	rmation	VIAL, MULTI-DOSE on Number or Monograph	Citation	Marke	ting Start D	ate Ma	arketing End Dat

GRAMA GRASS

grama grass injection, solution

	ion						
Product Type		HUMAN PRESCRIPTION D	RUG	Ite m	Code (Sourc	e) NI	DC:36987-2321
Route of Administrat	ion	INTRADERMAL, SUBCUT	ANEOUS				
Active Ingredient	Active Moi	ety					
	Ingr	edient Name			Basis of St	trength	Strength
BOUTELOUA GRACIL POLLEN - UNII:2XO083		NII: 2XO08315X1) (BOUTE	LOUA GRACIL	IS	BOUTELOUA POLLEN	GRACILIS	10000 [PNU] in 1 mL
Inactive Ingredie	nts						
		Ingredient Name					Strength
SODIUM CHLORIDE (JNII: 451W47IQ8	3X)					
SODIUM BICARBONA	TE (UNII: 8 MDF	5V39QO)					
SODIUM BICARBONA WATER (UNII: 059QF0)		5V39QO)					
	KO0R)	5V39QO)					
WATER (UNII: 059QF0)	KO0R)	5V39QO)					
WATER (UNII: 059QF01 PHENOL (UNII: 339NC(KO0R)	5V39QO)					
WATER (UNII: 059QF01 PHENOL (UNII: 339NCC Packaging	KOOR) G44TV)	sv39QO) skage Description	Marketi	ng Sta	nrt Date	Marketi	ing End Date
WATER (UNII: 059QF0) PHENOL (UNII: 339NC) Packaging # Item Code	KOOR) G44TV) Pac		Marketi	ng Sta	nrt Date	Marketi	ing End Date
WATER (UNII: 059QF01 PHENOL (UNII: 339NC0 Packaging Item Code NDC:36987-2321-1	<pre>KOOR) G44TV) F44TV Factor S mL in 1 V Factor F</pre>	ekage Description	Marketi	ng Sta	art Date	Marketi	ing End Date
WATER (UNII: 059QF0) PHENOL (UNII: 339NC) PHENOL (UNII: 339NC) Image: Comparison of the system of the syste	KOOR) G44TV) G44TV Pac 5 mL in 1 V 10 mL in 1 V	E kage Description IAL, MULTI-DOSE	Marketi	ng Sta	nrt Date	Marketi	ing End Date
 WATER (UNII: 059QF01) PHENOL (UNII: 339NC0) PHE	KOOR) G44TV) G44TV Pac 5 mL in 1 V 10 mL in 1 V 30 mL in 1 V	E kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	nrt Date	Marketi	ing End Date
 WATER (UNII: 059QF01) PHENOL (UNII: 339NC0) PHE	KOOR) G44TV) G44TV Pac 5 mL in 1 V 10 mL in 1 V 30 mL in 1 V	E kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	nrt Date	Marketi	ing End Date
 WATER (UNII: 059QF01) PHENOL (UNII: 339NC0) PHENOL (UNII: 339NC0) Ttem Code NDC:36987-2321-1 NDC:36987-2321-2 NDC:36987-2321-3 NDC:36987-2321-4 	 KOOR) G44TV) G44TV <li< td=""><td>Ekage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE</td><td>Marketi</td><td>ng Sta</td><td>nrt Date</td><td>Marketi</td><td>ing End Date</td></li<>	E kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	nrt Date	Marketi	ing End Date
WATER (UNII: 059QF0) PHENOL (UNII: 339NC) Packaging	KOOR) G44TV) G44TV) 5 mL in 1 V 10 mL in 1 V 30 mL in 1 50 mL in 1	E kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			nrt Date		ing End Date seting End Dat

JOHNSON GRASS

johnson grass injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2329
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	10000 [PNU] in 1 mL
I OLLEN - UNILS//VASD4III)	IOLLEN	III I IIIL

	ts					
		Ingredient Name				Strength
SODIUM CHLORIDE (U	NII: 451W47IQ	8 X)				
SODIUM BICARBONAT	E (UNII: 8 MDF	5V39QO)				
WATER (UNII: 059QF0K	00R)					
PHENOL (UNII: 339NCG4	44TV)					
Packaging						
# Item Code	Pa	ckage Description	Marketin	ig St	art Date Ma	arketing End Date
1 NDC:36987-2329-1	5 mL in 1 V	VIAL, MULTI-DOSE				
2 NDC:36987-2329-2	10 mL in 1	VIAL, MULTI-DOSE				
3 NDC:36987-2329-3	30 mL in 1	VIAL, MULTI-DOSE				
4 NDC:36987-2329-4	50 mL in 1	VIAL, MULTI-DOSE				
BLA	BLA102192			8/29/1	.972	
CULTIVATED (DAT					
cultivated oat injection	, solution					
Product Information	n					
Product Informatio Product Type	n	HUMAN PRESCRIPTION DI	RUG	Item	ı Code (Source)	NDC:36987-2337
		HUMAN PRESCRIPTION DI INTRADERMAL, SUBCUTA		Ite m	ı Code (Source)	NDC:36987-2337
Product Type				Ite m	ı Code (Source)	NDC:36987-2337
Product Type Route of Administratio	on	INTRADERMAL, SUBCUTA		Ite m	ı Code (Source)	NDC:36987-2337
Product Type Route of Administratio	on Active Moi	INTRADERMAL, SUBCUTA		Ite m	ı Code (Source) Basis of Streng	
Product Type Route of Administratio Active Ingredient/A	on Active Moi Ingre	INTRADERMAL, SUBCUTA	ANEOUS	Ite m		
Product Type Route of Administratio Active Ingredient/A AVENA SATIVA POLLE	on Active Moi Ingre	INTRADERMAL, SUBCUTA ety edient Name	ANEOUS	Ite m	Basis of Streng AVENA SATIVA	th Strength 10000 [PNU]
Product Type Route of Administration Active Ingredient/A AVENA SATIVA POLLE UNII:A7IKY24TR7)	on Active Moi Ingro N (UNII: A7IKY	INTRADERMAL, SUBCUTA ety edient Name Y24TR7) (AVENA SATIVA P	ANEOUS	Ite m	Basis of Streng AVENA SATIVA	th Strength 10000 [PNU] in 1 mL
Product Type Route of Administration Active Ingredient/A AVENA SATIVA POLLE UNII:A7IKY24TR7) Inactive Ingredient	on Active Moie Ingre N (UNII: A7IKY	INTRADERMAL, SUBCUTA ety edient Name Y24TR7) (AVENA SATIVA P Ingredient Name	ANEOUS	Item	Basis of Streng AVENA SATIVA	th Strength 10000 [PNU]
Product Type Route of Administration Active Ingredient/A AVENA SATIVA POLLE UNII: A7IKY24TR7) Inactive Ingredient SODIUM CHLORIDE (UN	on Active Moie Ingre N (UNII: A71K) ts	INTRADERMAL, SUBCUTA ety edient Name Y24TR7) (AVENA SATIVA P4 Ingredient Name 8X)	ANEOUS	Item	Basis of Streng AVENA SATIVA	th Strength 10000 [PNU] in 1 mL
Product Type Route of Administration Active Ingredient/A AVENA SATIVA POLLE UNII:A7IKY24TR7)	on Active Moie Ingre N (UNII: A71K) ts	INTRADERMAL, SUBCUTA ety edient Name Y24TR7) (AVENA SATIVA P4 Ingredient Name 8X)	ANEOUS	Item	Basis of Streng AVENA SATIVA	th Strength 10000 [PNU] in 1 mL

WATER (UNII: 059QF0KO0R)

PHENOL (UNII: 339NCG44TV)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36987-2337-1	5 mL in 1 VIAL, MULTI-DOSE		

Marketing Info		
4 NDC:36987-2337-4	50 mL in 1 VIAL, MULTI-DOSE	
3 NDC:36987-2337-3	30 mL in 1 VIAL, MULTI-DOSE	
2 NDC:36987-2337-2	10 mL in 1 VIAL, MULTI-DOSE	

QUACK GRASS

quack grass injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2355
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	10000 [PNU] in 1 mL			

Inactive Ingredients

Strength

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2355-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2355-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2355-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2355-4	50 mL in 1 VIAL, MULTI-DOSE		

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

CULTIVATED RYE

S S S S S S S S S S S S S S S S S S S
Basis of Strength Streng OLLEN - SECALE CEREALE 10000 [PNU POLLEN In 1 mL Strength Strength Image: Strength Image: Strength Image: Strength Image: Strength
OLLEN - SECALE CEREALE POLLEN 10000 [PNU in 1 mL Strength
OLLEN - SECALE CEREALE POLLEN 10000 [PNU in 1 mL Strength
OLLEN - SECALE CEREALE POLLEN 10000 [PNU in 1 mL Strength
POLLEN in 1 mL
arketing Start Date Marketing End Da
on Marketing Start Date Marketing End
08/29/1972
Item Code (Source) NDC:36987-23
S
s

Ingredient Name	Basis of Strength	Strength
LEYMUS CONDENSATUS POLLEN (UNII: 257GC6Q00Q) (LEYMUS CONDENSATUS		
POLLEN - UNII:257GC6QO0Q)	POLLEN	in 1 mL

Inactive Ingredient	S		
	Ingredient Name		Strength
SODIUM CHLORIDE (UN	NII: 451W47IQ8X)		
SODIUM BICARBONATI	E (UNII: 8MDF5V39QO)		
PHENOL (UNII: 339NCG4	4TV)		
WATER (UNII: 059QF0K0	00R)		
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

		r utilinge Debeription	Same sing o tart Date	
:	NDC:36987-2373-1	5 mL in 1 VIAL, MULTI-DOSE		
	2 NDC:36987-2373-2	10 mL in 1 VIAL, MULTI-DOSE		
3	B NDC:36987-2373-3	30 mL in 1 VIAL, MULTI-DOSE		
4	4 NDC:36987-2373-4	50 mL in 1 VIAL, MULTI-DOSE		

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

italian rye grass injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2381
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Ingredient Name	Basis of Stre	ngth	Strength
LOLIUM PERENNE SSP. MULTIFLORUM POLLEN (UNII: VJI0 WKK736) (LOLIUM PERENNE SSP. MULTIFLORUM POLLEN - UNII:VJI0 WKK736)	LOLIUM PERENNE MULTIFLORUM PO		10000 [PNU in 1 mL
Inactive Ingredients			
Ingredient Name		Str	ength
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
PHENOL (UNII: 339NCG44TV)			
WATER (UNII: 059QF0KO0R)			

# Item Code	Pac	kage Description	Marke	ting Sta	rt Date	Ma	arketi	ng End Date
1 NDC:36987-2381-1	5 mL in 1 V	IAL, MULTI-DOSE						-
2 NDC:36987-2381-2	10 mL in 1	VIAL, MULTI-DOSE						
B NDC:36987-2381-3		VIAL, MULTI-DOSE						
NDC:36987-2381-4		VIAL, MULTI-DOSE						
Marketing Info	rmation							
Marketing Category	Applicatio	on Number or Monograp	h Citation	Marke	ting Start D	ate	Mark	eting End Dat
BLA	BLA102192			08/29/19	72			
				1				
SALT GRASS								
alt grass injection, so	lution							
Product Information	m							
	,11		DUC	.	0 1 (0			0.000.000
Product Type		HUMAN PRESCRIPTION D	RUG	lte m	Code (Sour	ce)	ND	C:36987-2391
Route of Administratio)n	INTRADERMAL, SUBCUT	ANEOUS					
A - 4° T	Active Mai	- 4						
Active ingredient/					Basis of	Stron	ath	Strongth
J.	Ingr	e ty e dient Name : GOA51670 YV) (DISTICHL	IS SPICATA F	POLLEN	Basis of S		-	Strength 10000 [PNU]
DISTICHLIS SPICATA P	Ingr	edient Name	IS SPICATA F	POLLEN			-	
DISTICHLIS SPICATA P UNII:GOA51670 YV)	Ingr Ollen (UNII	edient Name : GOA51670 YV) (DISTICHL	IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P UNII:GOA51670YV)	Ingr OLLEN (UNII	edient Name : GOA51670 YV) (DISTICHL Ingredient Name	.IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU]
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient	Ingr OLLEN (UNII S NII: 451W47IQ8	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X)	IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT	Ingr OLLEN (UNII S NII: 451W47IQ E (UNII: 8MDF	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X)	IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P • UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT	Ingr OLLEN (UNII S NII: 451W47IQ E (UNII: 8MDF	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X)	IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P - UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339NCG4	Ingr OLLEN (UNII ts NII: 451W47IQ8 E (UNII: 8 MDF 44TV)	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X)	IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P • UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339NCG4	Ingr OLLEN (UNII ts NII: 451W47IQ8 E (UNII: 8 MDF 44TV)	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X)	IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339 NCG4 WATER (UNII: 059 QF0 K	Ingr OLLEN (UNII ts NII: 451W47IQ8 E (UNII: 8 MDF 44TV)	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X)	IS SPICATA F	POLLEN	DISTICHLIS		TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339 NCG4 WATER (UNII: 059 QF0 K Packaging	Ingr OLLEN (UNII S NII: 451W47IQ8 E (UNII: 8 MDF 44TV) 00 R)	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X)		POLLEN	DISTICHLIS POLLEN	SPICA	TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0K4 Packaging I tem Code	Ingr OLLEN (UNII ts NII: 451W47IQ8 E (UNII: 8 MDF 44TV) 00 R) Pac	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X) 5V39QO)			DISTICHLIS POLLEN	SPICA	TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339 NCG4 WATER (UNII: 059 QF0 K VATER (UNII: 059 QF0 K I tem Code	Ingr OLLEN (UNII S NII: 451W47IQ8 E (UNII: 8 MDF 44⊤V) 00 R) Pac 5 mL in 1 V	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X) 5V39QO)			DISTICHLIS POLLEN	SPICA	TA	10000 [PNU] in 1 mL
Distichlis spicata P UNII:GO A51670 YV) Inactive Ingredient GO DIUM CHLO RIDE (UI GO DIUM CHLO RIDE (UI GO DIUM BICARBO NAT PHENOL (UNII: 339 NCG4 VATER (UNII: 059 QF0 K Packaging Item Code NDC:36987-239 1-1 NDC:36987-239 1-2	Ingr Ingr <	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X) 5V39QO) :kage Description IAL, MULTI-DOSE			DISTICHLIS POLLEN	SPICA	TA	10000 [PNU] in 1 mL Strength
- UNII:GOA51670YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0K4 Packaging	Ingr Ingr <	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X) 5V39QO) :kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE			DISTICHLIS POLLEN	SPICA	TA	10000 [PNU] in 1 mL
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339 NCG4 WATER (UNII: 059 QF0 K WATER (UNII: 059 QF0 K TER (UNII: 059 QF0 K MATER (UNII: 059 QF0 K M M M M M M M M M M M M M M M M M M M	Ingr Ingr <	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X) 5V39QO) : Kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			DISTICHLIS POLLEN	SPICA	TA	10000 [PNU] in 1 mL
Distichlis spicata P UNII:GO A51670 YV) Inactive Ingredient SO DIUM CHLO RIDE (UI SO DIUM BICARBO NAT PHENOL (UNII: 339 NCG4 WATER (UNII: 059 QF0 K Packaging I Item Code NDC:36987-2391-1 NDC:36987-2391-3 NDC:36987-2391-3 NDC:36987-2391-4	Ingr Ingr <	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X) 5V39QO) : kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marke	ting Sta	DISTICHLIS POLLEN	S PIC A	arketi	10000 [PNU] in 1 mL Strength ng End Date
DISTICHLIS SPICATA P UNII:GOA51670 YV) Inactive Ingredient SODIUM CHLORIDE (UI SODIUM BICARBONAT PHENOL (UNII: 339 NCG4 WATER (UNII: 059 QF0 K WATER (UNII: 059 QF0 K I tem Code NDC:36987-2391-1 NDC:36987-2391-3	Ingr Ingr <	edient Name : GOA51670 YV) (DISTICHL Ingredient Name 3X) 5V39QO) : Kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marke	ting Sta	DISTICHLIS POLLEN	S PIC A	arketi	10000 [PNU] in 1 mL

VELVET GRAS	SS							
elvet grass injection	, solution							
D								
Product Informati	ion							
Product T ype		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sou	rce)	ND	C:36987-2403
Route of Administrat	ion	INTRADERMAL, SUBCUTA	NEOUS					
Active Ingredient/	Active Moi	ety						
	Ingr	edient Name			Basis of	Streng	th	Strength
DISTICHLIS SPICATA - UNII:GOA51670YV)	POLLEN (UNI	: GOA51670YV) (DISTICHLIS	SPICATA PO	LLEN	DISTICHLIS POLLEN	SPICAT	A	10000 [PNU] in 1 mL
Inactive Ingredier	nts							
		Ingredient Name						Strength
SODIUM CHLORIDE (U	JNII: 451W47IQ	0						
SODIUM BICARBONA	TE (UNII: 8 MDF	75V39QO)						
PHENOL (UNII: 339NCC	G44TV)							
WATER (UNII: 059QF01	KO0R)							
Packaging								
	Pa	ckage Description	Marketi	ng Sta	rt Date	Mar	rketi	ng End Date
# Item Code		c kage Description /IAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketi	ng End Date
# Item Code 1 NDC:36987-2403-1	5 mL in 1 V	c kage Description /IAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketi	ng End Date
# Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2	5 mL in 1 V 10 mL in 1	VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketi	ng End Date
Figure 1 Figure 2 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketi	ng End Date
 # Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketi	ng End Date
 # Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4 	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 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4 	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 I			ng End Date seting End Dat
Item Code I NDC:36987-2403-1 NDC:36987-2403-2 NDC:36987-2403-3 NDC:36987-2403-3 NDC:36987-2403-4	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 I			
# Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4 Marketing Info Marketing Category BLA	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	Marke	ting Start I			
# Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4 Marketing 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 40 mL in 1 10 mL	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start I			
# Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4 Marketing 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 40 mL in 1 10 mL	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start I			
 Item Code NDC:36987-2403-1 NDC:36987-2403-2 NDC:36987-2403-3 NDC:36987-2403-4 Marketing Info Marketing Category BLA CULTIVATED cultivated wheat inject	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Applicatio BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start I			
 # Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4 Marketing Info Marketing Category BLA CULTIVATED cultivated wheat inject Product Information	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Applicatio BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation 0	Marke 8/29/19	ting Start I	Date M	Mark	
Item Code 1 NDC:36987-2403-1 2 NDC:36987-2403-2 3 NDC:36987-2403-3 4 NDC:36987-2403-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 40 mL in 1 10 mL	on Number or Monograph	Citation 0	Marke 8/29/19	ting Start I 72	Date M	Mark	e ting End Dat

Active Ingredient/Active Moiety						
	Ingredient Name	Basis of Strength	Strength			

F RITICUM AESTIVUM UNII:F1KAH8374D)	POLLEN (UNII: F1KAH8374D) (TRITICUM AESTIVUM	1 POLLEN	TRITICUM AEST POLLEN	IVUM	10000 [PNU] in 1 mL
Inactive Ingredier	ıts				
	Ingredient Name				Strength
SODIUM CHLORIDE (U	JNII: 451W47IQ8X)				
SODIUM BICARBONA	FE (UNII: 8 MDF5V39QO)				
PHENOL (UNII: 339NC)	G44TV)				
WATER (UNII: 059QF0)	KO0R)				
Packaging					
00	Package Description Mar	ceting Sta	rt Date	Market	ting End Date
# Item Code	Package Description Mar 5 mL in 1 VIAL, MULTI-DOSE	seting Sta	urt Date	Market	ting End Date
# Item Code 1 NDC:36987-2411-1	U	ceting Sta	rt Date	Market	ting End Date
 # Item Code 1 NDC:36987-2411-1 2 NDC:36987-2411-2 	5 mL in 1 VIAL, MULTI-DOSE	ceting Sta	nrt Date	Market	ting End Date
# Item Code 1 NDC:36987-2411-1 2 NDC:36987-2411-2 3 NDC:36987-2411-3	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE	ceting Sta	rt Date	Market	ting End Date
First staging # Item Code 1 NDC:36987-2411-1 2 NDC:36987-2411-2 3 NDC:36987-2411-3 4 NDC:36987-2411-4	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	ceting Sta	nrt Date	Marke	ting End Date
# Item Code 1 NDC:36987-2411-1 2 NDC:36987-2411-2 3 NDC:36987-2411-3	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	ceting Sta	nrt Date	Market	ting End Date
# Item Code 1 NDC:36987-2411-1 2 NDC:36987-2411-2 3 NDC:36987-2411-3	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	eting Sta	urt Date	Market	ting End Date
# Item Code 1 NDC:36987-2411-1 2 NDC:36987-2411-2 3 NDC:36987-2411-3 4 NDC:36987-2411-4	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		eting Start Date		ting End Date keting End Da

WEST WHEAT GRA	SS				
vest wheat grass injection, so	olution				
Product Information					
Product T ype	HUMAN PRESCRIPTION DRUG	Ite m	Code (Source)	NDC:3	6987-2419
Route of Administration	INTRADERMAL, SUBCUTANEOUS				
Active Ingredient/Active	Moiety				
	Ingredient Name		Basis of Streng	th	Strength
PASCOPYRUM SMITHII POLLEN (UNII: 6AU0ZD8T10) (PASCOPYRUM SMITHIIPASCOPYRUM SMPOLLEN - UNII: 6AU0ZD8T10)POLLEN)000 [PNU] n 1 mL
Inactive Ingredients					
	Ingredient Name			St	rength
SODIUM CHLORIDE (UNII: 451W	V47IQ8X)				
SODIUM BICARBONATE (UNII:	8MDF5V39QO)				
PHENOL (UNII: 339NCG44TV)					

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:36987-2419-1	5 mL in 1 VIAL, MULTI-DOSE					
2 NDC:36987-2419-2	10 mL in 1 VIAL, MULTI-DOSE					
3 NDC:36987-2419-3	30 mL in 1 VIAL, MULTI-DOSE					
4 NDC:36987-2419-4	50 mL in 1 VIAL, MULTI-DOSE					
Marketing Information						
Marketing Category	Application Number or Monograph Ci	tation Marketing Start Date	Marketing End Date			
BLA	BLA102192	08/29/1972				

	NDC:36987-2429-2	10 mL in 1 VIAL, MULTI-DOSE30 mL in 1 VIAL, MULTI-DOSE					
1	NDC:36987-2429-1	5 mL in 1 VIAL, MULTI-DOSE					
#	Item Code	Package Description	Marketin	g Sta	art Date	Marke	ting End Date
P	ackaging						
vv	AIER (UNII. 059QF0RO	() () () () () () () () () () () () () (
	IENOL (UNII: 339NCG44 ATER (UNII: 059QF0KO						
	DIUM BICARBONATE						
S	DDIUM CHLORIDE (UN	II: 451W47IQ8X)					
		Ingredient Name					Strength
Iı	active Ingredients	3					
	NII:766QT72BK6)				POLLEN		in 1 mL
B	ROMUS INERMIS POLI	Ingredient Name LEN (UNII: 766QT72BK6) (BROMUS INE	RMIS POLLEN -		Basis of S BROMUS IN	-	Strength 10000 [PNU]
A	ctive Ingredient/A				Dacia of (tuonath	Stuonath
•							
N	ute of Automisti auto						
р	oute of Administration		HUMAN PRESCRIPTION DRUG Item Code (Source)				
	roduct T ype		RUG	Ito m	Code (Sour		NDC:36987-2429
	roduct Information						

08/29/1972

SMOOTH BRO							
Product Information	on						
Product T ype	HUN	AN PRESCRIPTION DF	RUG	Ite m	Code (Sourc	e)	NDC:36987-2437
Route of Administrati	on INT	RADERMAL, SUBCUTA	NEOUS				
Active Ingredient/	Active Moiety						
	Ingredie	nt Name			Basis of S	trength	Strength
BROMUS INERMIS POI UNII:766QT72BK6)	L LEN (UNII: 766QT	72BK6) (BROMUS INEI	RMIS POLLEN	-	BROMUS INE POLLEN	RMIS	10000 [PNU] in 1 mL
Inactive Ingredien	ts						
	I	ngredient Name					Strength
SODIUM CHLORIDE (U							
SODIUM BICARBONAT	E (UNII: 8 MDF5V39	Q0)					
PHENOL (UNII: 339NCG							
WATER (UNII: 059QF0K	.00K)						
Packaging							
# Item Code	Packag	e Description	Marketi	ng Sta	rt Date	Mark	eting End Date
1 NDC:36987-2437-1	5 mL in 1 VIAL,	MULTI-DOSE					
2 NDC:36987-2437-2	10 mL in 1 VIAL	, MULTI-DOSE					
3 NDC:36987-2437-3	30 mL in 1 VIAL	, MULTI-DOSE					
4 NDC:36987-2437-4	50 mL in 1 VIAL	, MULTI-DOSE					
Marketing Info	rmation						
Marketing Category	Application Nu	mber or Monograph	Citation	Marke	ting Start Da	nte Ma	rketing End Date
BLA	BLA102192		0	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