STANDARDIZED ORCHARD GRASS POLLEN - standardized orchard grass pollen injection, solution
STANDARDIZED PERENNIAL RYE GRASS POLLEN - standardized perennial rye grass pollen injection, solution
STANDARDIZED TIMOTHY GRASS POLLEN - standardized timothy grass pollen injection, solution
STANDARDIZED REDTOP GRASS POLLEN - standardized redtop grass pollen injection, solution
STANDARDIZED KENTUCKY (JUNE) BLUEGRASS POLLEN - standardized kentucky (june) bluegrass pollen injection, solution
STANDARDIZED MEADOW FESCUE GRASS POLLEN - standardized meadow fescue grass pollen injection, solution
STANDARDIZED SWEET VERNAL GRASS POLLEN - standardized sweet vernal grass pollen injection, solution
STANDARDIZED BERMUDA GRASS POLLEN - standardized bermuda grass pollen injection, solution
Nelco Laboratories, Inc.

Allergenic Extract

WARNINGS

Standardized allergenic extract is intended for use by physicians who are experienced in the administration of standardized (BAU/mL) allergenic extracts for immunotherapy and the emergency care of anaphylaxis, or for use under the guidance of an allergy specialist. For previously untreated patients, the initial dose must be based on skin testing as described in the dosage and administration section of this insert. **Standardized Grass Pollen extract is NOT directly interchangeable with Grass Pollen extracts labeled in AU/mL, or with non-standardized Grass Pollen extracts.**

This product should not be injected intravenously. Deep subcutaneous routes have proven to be 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 beta-blocker 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 bronchodialators.[(1)] **(See Precautions)**

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

DESCRIPTION

Standardized Grass Pollen Extracts include: Orchard *(Dactylis glomerata)*, Perennial Rye *(Lolium perenne)*, Timothy *(Phleum pratense)*, Redtop *(Agrostis alba)*, Kentucky (June) Bluegrass *(Poa pratensis)*, Bermuda *(Cynodon dactylon)*, Meadow Fescue *(Festuca elatior)*, Sweet Vernal *(Anthoxanthum odoratum)*. The standardized grass pollen extract is prepared by extracting raw pollen material at a ratio of either 1:5 w/v, 1:6.66 w/v or 1:10 w/v in Cocas fluid containing 0.5% NaCl, 0.275% $NaHCO_3$, WFI and 0.4%

phenol as preservative. Following extraction, a calculated amount of glycerin is added to make a 50%(v/v) glycerinated solution. Standardized Grass Pollen extracts have potency designations of 10,000 BAU/mL and 100,000 BAU/mL except Bermuda Grass (10,000 BAU/mL only). Extracts with a potency of 10,000 BAU/mL are diluted from the 100,000 BAU/mL lots with Glycerol Saline 50%(v/v). The Glycerol Saline 50%(v/v) solution consists of Glycerin and Salts and Buffered Diluent whose ingredients are 0.5% NaCl, 0.08% Na_2HPO_4, 0.036% KH_2PO_4, WFI and 0.4% phenol as a preservative. All extracts are aseptically filled in sterile containers. Standardized pollen extracts are intended for administration by prick-puncture or intradermal routes when used for diagnostic purposes and administered subcutaneously when used for immunotherapy injection.

Standardized grass pollen extracts labeled in BAU/mL are not interchangeable with grass pollen extracts labeled in AU/mL or with non-standardized grass pollen extracts. The Bioequivalent Allergy Unit (BAU), the potency unit used for all Standardized Pollen Extracts, replaces the previous unitage for these products. Bioequivalent Allergy Units were assigned to the FDA, Center for Biologics Evaluation and Research (CBER) reference extracts, based on quantitative intradermal skin test results. BAU's are intended to assure that the labeled unitage of different allergenic extracts will correspond to the expected clinical response in sensitive patients. References labeled 10,000 BAU/mL can be diluted one half million fold to produce an intradermal sum of erythema diameter response of 50mm in highly puncture reactive subjects. 100,000 BAU/mL can be diluted 1:5 million fold to yield the same intradermal response.(2) The assignment of BAU/mL to standardized grass pollen extracts, is accomplished by an ELISA assay comparing the extract to the CBER reference.

Previously, the potency / concentration of grass mixtures was designated based on the manufacturing strength, e.g. 1:10 w/v or 1:20 w/v, or in PNU's/mL. For grass mixtures containing standardized extracts, the potency will reflect the contribution of each individual component in the mixture, i.e., the actual potency of each component will be listed on a per mL basis. In addition, because the individual components may be cross-reactive, an additional caution statement, "due to cross reactivity, total potency may be 100,000 BAU/mL," will be added to the label.

CLINICAL PHARMACOLOGY

The mode of action of allergenic extracts is still under investigation. 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 therapeutic immunotherapy, the effect is an increase in immunoglobulin G (IgG) and an increased T suppresser lymphocyte which interferes with the allergic response.(3) Although immunotherapy may be considered as immunosuppression, in which the production of allergen-specific antibody is inhibited, the mechanism of the clinical effectiveness of immunotherapy remains under investigation. Assignment of BAU/mL potency designation was determined based on Puncture and Intradermal Data with CBER Grass References.(2)

Puncture & Intradermal Data with CBER Grass References

A. Puncture Data with 10,000 BAU/mL Grass Extracts *(bifurcated needle)*

Reference Pollen	FDA Lot #	N	P Σ E (mm) Mean	P Σ E (mm) Range	P Σ W (mm) Mean	P Σ W (mm) Range
Bermuda	E4-Ber	15	90.3	43-123	15.7	7-31
June	E3-Jkb	15	77.3	47-107	15.9	6-28
Meadow Fescue	E4-Mf	15	81.1	57-115	11.9	7-22
Orchard	E4-Or	15	84.3	57-111	14.1	9-19
Perennial Rye	E10-Rye	15	92.3	73-135	17.5	6-36

Redtop	E4-Rt	15	77.1	42-98	14.1	8-19
Sweet Vernal	E4-Sv	15	81.2	28-123	15.7	8-30
Timothy	E6-Ti	15	88.3	51-109	16.9	8-40

B. Intradermal Dose (BAU_{50}) of CBER Grass References for 50 mm Sum of Erythema

Reference Pollen	FDA Lot #	BAU_{50}/mL Mean	BAU_{50}/mL Range
Bermuda	E4-Ber	0.02	0.4-0.0003
June	E3-Jkb	0.02	0.1-0.004
Meadow Fescue	E4-Mf	0.02	0.9-0.002
Orchard	E4-Or	0.02	1.9-0.002
Perennial Rye	E10-Rye	0.02	0.7-0.002
Redtop	E4-Rt	0.02	0.8-0.004
Sweet Vernal	E4-Sv	0.02	1.0-0.002
Timothy	E6-Ti	0.02	0.6-0.002

C. Potency of Selected Glycerinated Non-Standardized Grasses distributed by Nelco Laboratories, Inc.

Extract	Weight/ Volume	# of Lots	Range (BAU/mL)
Orchard	1:10	3	144,200-155,300
Bermuda	1:20; 1:10	3	7,800-12,560
Sweet Vernal	1:10	3	180,600-236-200
Timothy	1:10	2	99,100-110,200
Perennial Rye	1:20; 1:10	2	77,900-162,100
June	1:20; 1:10	3	79,000-111,500
Redtop	1:20; 1:10	3	179,900-300,500
Meadow Fescue	1:20	2	128,800-294,800
* Note: These extracts were previously distributed.			

The potency of the glycerinated non-standardized grass extracts are equivalent to or exceed the potency for standardized grass pollen extract (Range for equivalence to CBER reference labeled 100,000 BAU/mL is 67,300 to 148,600, and range for equivalence to CBER reference labeled 10,000 BAU/mL is 6,730 to 14,860).

INDICATIONS AND USAGE

Standardized Pollen Extract is intended for use in the diagnosis and therapy of pollen allergic patients as established by allergy history and skin test reactivity. Standardized Grass Pollen extracts labeled in BAU/mL are not interchangeable with Grass Pollen extracts labeled in AU/mL or with non-standardized Grass Pollen extracts. The 10,000 BAU/mL dose form is indicated for percutaneous testing. If negative, 100,000 BAU/mL dose form can be used for percutaneous testing. For immunotherapy, availability of 10,000 and 100,000 BAU/mL dosages facilitates safe switching. (See Dosage & Administration)

The use of standardized grass pollen extracts is indicated for hyposensitization treatment and may be used as part of the over-all management of the allergic patient. Treatment of grass sensitive patients consists of using specific standardized grass products of up to and including doses of 100,000 BAU/mL (up to 10,000 BAU/mL for Bermuda grass) or stock mixtures of standardized grass products.

Stock mixtures of standardized grass extracts are particularly useful in hyposensitization treatment when multiple allergies to grasses are diagnosed. For previously untreated patients, the 10,000 BAU/mL concentrates can be used to formulate dosages. If tolerated, the concentrates can be inceased to 100,000 BAU/mL dose formulation.

CONTRAINDICATIONS

Standardized Pollen extract should not be used if the patient has asthma, cardiovascular disease, emphysema, diabetes, bleeding diathesis or pregnancy, unless a specific diagnosis of type 1 allergy to Pollen is made based on skin testing and the benefits of treatment outweigh the risks of an adverse reaction during testing or treatment. Pollen extract is not indicated for use in patients who are not clinically allergic to pollen or who are not skin reactive to pollen. Limitations on treatment should be considered when treating the very young, or geriatric patients or those suffering from auto-immune disorders or severe and unstable allergic disorders.

WARNINGS

Concentrated extracts must be diluted with sterile diluent prior to first use on a patient for treatment or intradermal testing.

DO NOT INJECT INTRAVENOUSLY.

All concentrates of allergenic extracts have the ability to cause serious local and systemic reactions including death in sensitive patients.[(3)] **(See Adverse Reactions)**

Standardized Pollen extracts should be used with caution when treating patients who exhibit hypersensitivity to standardized pollen extracts as confirmed by diagnostic testing.

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.

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. Patients should be observed for 30 minutes after any test.

Information for Patients: All concentrates of allergenic extracts including standardized pollen extracts, have the potential to cause serious local and systemic reactions including death, in sensitive patients. To minimize this potential hazard, the relative sensitivity of the patient must be assessed from an allergic history and clinical observations. In certain individuals, life-threatening reactions may occur. 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 and to wait in the office at least 30 minutes after an injection.

Drug Interactions: 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, although

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 a long acting antihistamine manufacturer for more information.

Extreme caution should be taken when using allergenic extracts in patients who are taking beta-blockers. Patients receiving beta-blockers may not be responsive to epinephrine or inhaled bronchodialators.

Carcinogenesis, mutagenesis, impairment of fertility.

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

Pregnancy: Category C. Animal reproduction studies have not been conducted with allergenic extract. It is not known whether this extract can cause fetal harm when administered to a pregnant women or can effect reproduction capacity. Due to histamines ability to induce uterine contractions, allergenic extract 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.(4)

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. In rare instances this may result in 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 Overdosage)**

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 indicated.

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

An overdose can cause both local and systemic reactions. An overdose is prevented by careful observation and questioning the patient about reactions to previous extract injections.

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 0.1mL, for

children 2 to 6 years it is 0.15mL, for children 6-12 years it is 0.2mL. Patients unresponsive to epinephrine may be treated with intravenous bronchodilators. Studies on asthmatic subjects reveal that plasma concentrations of theophylline of 5 to 20 µg/mL are associated with therapeutic effects. Toxicity is particularly apparent at concentrations greater than 20 µg/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 µg/mL for patients not previously receiving theophylline. (Mitenko, Ogilive 1973; Nicholoson, 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 0.5mL of the 0.5% solution for Isoproterenol HCl. The Albuterol inhaler delivers approximately 90mcg 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 340mcg Isoetharine. The average dose is one to two inhalations. Persistent wheezing may necessitate intravenous aminophylline treatment. For profound shock and hypotension, intravenous fluids, vasopressors and oxygen may also be needed. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require oxygen, intubation and the use of life support systems.

DOSAGE AND ADMINISTRATION

It is imperative that the physician determine a safe initial dose. Patients being switched from one lot of Standardized Pollen to another lot of Standardized Pollen (from the same or different manufacturers) should have the initial dose from the new lot reduced by 75%. For patients being switched from non-standardized extract to a standardized extract, the selection of dose needs to be based on the dose of the extract currently administered and the relative potency with regards to the standardized extract. **(See Clinical Pharmacology Table C for a comparison of standardized and non-standardized pollen extracts).** Side by side comparison of wheal and erythema by skin testing of standardized and non-standardized extract can be carried out to determine comparability of doses selected.

For safe and effective use of allergenic extracts, sterile solutions, vials, syringes, etc. should be used and aseptic precautions followed when making dilution's and giving injections. The usual precautions to be observed in administering extracts are necessary. A sterile tuberculin syringe graduated in 0.1mL units to measure each dose for the prescribed dilution should be used.

After therapeutic injections patients should always be observed for at least 30 minutes. If adverse reactions appear, the next therapeutic injection of extract should be reduced to the dose which does not elicit a reaction and subsequent doses increased more slowly.

Recommended dosage and range: (Scratch or Prick tests)

The general method of making a scratch test is to first scarify the skin and then apply a drop of extract to the scratch. Make scarifications at least 2.5 cm apart. Hold the scarifier between thumb and index finger, press the sharp edge of the instrument against the skin and twirl instrument rapidly. The scratch should disrupt the outer layers of epidermis but should not produce immediate oozing of blood. One drop (0.05mL) of extract is rubbed or applied into each scratch. 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.

The concentration of Standardized Pollen extract for Scratch or Prick-puncture testing is prepared using 10,000 BAU/mL. If negative, 100,000 BAU/mL can be used to determine sensitivity of the patient.

Recommended dosage and range: *(Intradermal tests)*

Patients with a negative scratch or prick-puncture test:

Patients who do not react to a valid scratch or prick- puncture test should be tested intradermally with

0.05mL of a 50 BAU/mL extract solution. If this test is negative, a second intradermal test may be performed using a 100 BAU/mL extract dilution. The negative puncture test control must be diluted appropriately for intradermal use.

To prepare a 50 BAU/mL dilution from Nelco's

10,000 BAU/mL vial:

Take 5.0 mL of the 10,000 BAU/mL + 5.0mL of diluent

equals Vial A at 5,000 BAU/mL.

Take 1.0 mL of Vial A + 9.0 mL diluent equals

Vial B at 500 BAU/mL.

Take 1.0 mL of Vial B + 9.0 mL diluent equals

Vial C at 50 BAU/mL.

Patients tested only by the intradermal method: (See table B) Patients being suspected of being highly allergic should be tested with 0.05 mL of a 0.1 BAU/mL dilution. A negative test should be followed by repeat tests using progressively stronger concentrations until the maximal recommended strength of 100 BAU/mL is reached. The negative puncture test control must be diluted appropriately for intradermal use. To prepare this dilution follow the tenfold dilution series chart for therapeutic allergens.

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.

Preparation Instructions: To prepare a dilution for intradermal and therapeutic use, one starts with 10,000 BAU/mL stock concentrate and makes a 1:10 dilution by adding 1.0 mL of the concentrate to 9.0mL of sterile diluent. Subsequent dilutions are made in similar manner.

TEN-FOLD DILUTION SERIES

Dilution	Extract	Diluent mL	BAU/mL
0	Concentrate	0	10,000
1	1 mL concentrate	9	1,000
2	1 mL dilution #1	9	100
3	1 mL dilution #2	9	10
4	1 mL dilution #3	9	1
5	1 mL dilution #4	9	0.1
6	1 mL dilution #5	9	0.01

Recommended dosage and range: (Therapeutic)

Dosage of allergenic extracts is a highly individualized matter and varies according to the degree of sensitivity of the patient, the clinical response and tolerance to the extract administered during the injection regimen. The dosage of allergenic extract does not vary significantly with the respiratory allergic disease under treatment. In patients who appear to be highly sensitive by history and skin test, the initial dose of the extract should be 0.05mL of 5 BAU/mL which results in a dosage of 0.25 BAU. Patients with lesser sensitivity may be started using 1 BAU/mL. 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. Any evidence of systemic reaction is an indication for a significant reduction (at least 50%) in the subsequent dose. Any evidence of a local or generalized reaction requires a reduction in dosage. After therapeutic injections, patients should always be observed for at least 20 minutes. If adverse reactions appear, the next therapeutic injection of extract

should be reduced to the dose which dose not elicit a reaction and subsequent doses increased more slowly. The upper limits of dosage have not been established. Doses larger than 0.2 mL of 10,000 BAU/mL may be painful due to glycerin content. Dosage use of up to 100,000 BAU/mL is determined by patient response and administered at the discretion of the physician.

Suggested Dosage Charts **(Note Disclaimer)*

*****_This is a suggested dose chart only. Dose regimen has not been subjected to adequate and well controlled studies to determine safety and efficacy._

Please read entire instructions before commencing immunotherapy. Observe patients for 30 minutes after an injection. Note: Certain individuals may not tolerate this suggested schedule. The physician may need to adjust both the dosage and interval accordingly.

Suggested Treatment Schedule

Vial #	Injection #	Volume (mL)
1 *(5 BAU/mL)*	1	0.05
1	2	0.10
1	3	0.15
1	4	0.20
1	5	0.30
1	6	0.40
1	7	0.50
2 *(50 BAU/mL)*	8	0.05
2	9	0.10
2	10	0.15
2	11	0.20
2	12	0.30
2	13	0.40
2	14	0.50
3 *(500 BAU/mL)*	15	0.05
3	16	0.10
3	17	0.15
3	18	0.20
3	19	0.30
3	20	0.40
3	21	0.50
4 *(5,000 BAU/mL)*	22	0.05
4	23	0.07
4	24	0.10
4	25	0.15
4	26	0.20
4	27	0.25
4	28+++	0.25

Note: Maintenance dose is that dose which provides symptomatic relief or the strongest dose that can be tolerated by the patient. Therefore, a physician must determine each patient's maintenance dose.

Intervals between doses: The optimal interval between doses of allergenic extract has not been definitely established. However, as it is customary practiced, injections are given once or twice per week until the maintenance dose of extract is reached. At this time, the injection interval may be increased to 2 weeks, then 3 weeks and finally to 4 weeks. If the patient does not return for 6-8 weeks after the last injection, the dose should be reduced to 25% of the last dose. If longer than 8 weeks, a dose reduction of 1,2, or 3 dilutions may be made depending on a consideration of the components and the patient's sensitivity.(3) The dosage and the interval between injections may need to be modified according to the clinical response of the patient. When switching patients to a new extract the initial dose should be reduced 3/4 so that 25% of previous dose is administered.

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.

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

HOW SUPPLIED

Diagnostic Allergens:

Scratch or Prick test:

10,000 BAU/mL or 100,000 BAU/mL contained in

50% glycerin (v/v)

in 5mL dropper vials.

Intradermal test:

100 BAU/mL in 5mL or 10mL sterile multiple dose vials.

Concentrate of Extract for Therapeutic Use Allergens:

10,000 BAU/mL and 100,000 BAU/mL are supplied in 5mL, 10mL, 50mL multiple dose vials.

STORAGE

The expiration date of Standardized Pollen extract containing 10,000 BAU/mL or 100,000 BAU/mL in 50% glycerin (v/v) is listed on the container label. Store extracts upon arrival at 2° to 8 °C and keep them in this range during office use.

WARRANTY 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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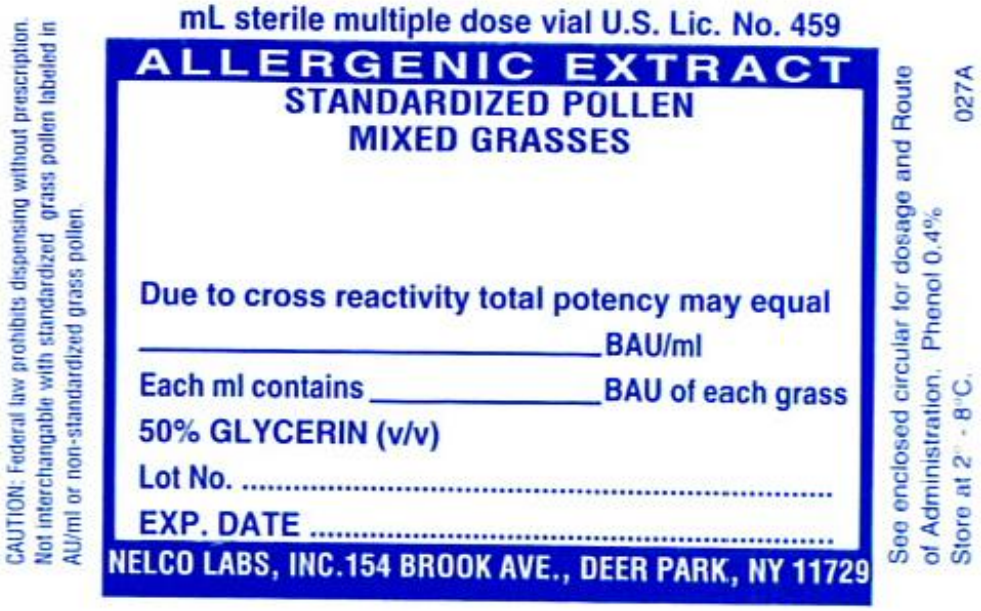
2. Turkeltaub,P., Rastogi,S. Quantitative Intradermal Procedure for Evaluation of Subject Sensitivity to Standardized Allergenic Extracts and for Assignment of Bioequivalent Allergy Units to Reference Preparations using ID50EAL. Methods & Procedures Manual, CBER,1993.

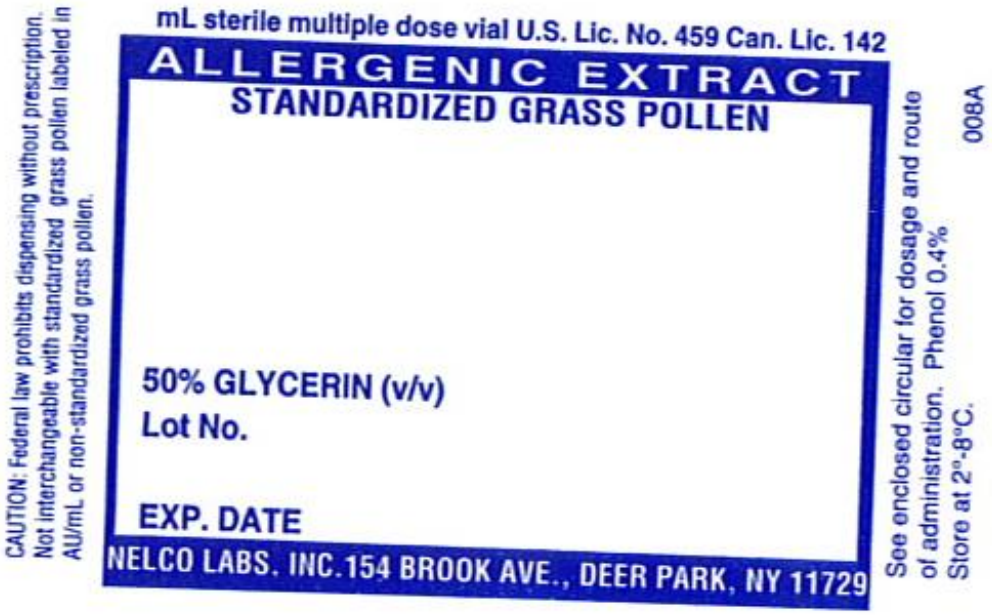
3. Lockey, R.F., Bukantz, S.C., Allergen Immunotherapy. New York,NY: Marcel Dekker Inc., 1991.

4. 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.

5. Reid,M.J., Lockey,R.F., Turkeltaub,P.C., Platts-Mills,T.A.E., Survey of fatalities from skin testing and immunotherapy 1985-1989. Journal of Allergy Clin. Immunol. 92 (1): 6-15, July 1993.

CONTAINER LABELING





STANDARDIZED ORCHARD GRASS POLLEN

standardized orchard grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2346
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36987-2346-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2346-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2346-3	30 mL in 1 VIAL, MULTI-DOSE		

4	NDC:36987-2346-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102198	02/10/1998	

STANDARDIZED PERENNIAL RYE GRASS POLLEN

standardized perennial rye grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2390
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2390-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2390-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2390-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2390-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102200	02/10/1998	

STANDARDIZED TIMOTHY GRASS POLLEN

standardized timothy grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2402
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36987-2402-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2402-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2402-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2402-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102202	02/10/1998	

STANDARDIZED REDTOP GRASS POLLEN

standardized redtop grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2364
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36987-2364-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2364-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2364-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2364-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102192	02/10/1998	

STANDARDIZED KENTUCKY (JUNE) BLUEGRASS POLLEN

standardized kentucky (june) bluegrass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2428
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2428-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2428-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2428-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2428-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102196	02/10/1998	

STANDARDIZED MEADOW FESCUE GRASS POLLEN

standardized meadow fescue grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2320
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FESTUCA PRATENSIS POLLEN (UNII: A0WFQ8P6N1) (FESTUCA PRATENSIS POLLEN - UNII:A0WFQ8P6N1)	FESTUCA PRATENSIS POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2320-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2320-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2320-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2320-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102197	02/10/1998	

STANDARDIZED SWEET VERNAL GRASS POLLEN

standardized sweet vernal grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2400
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2400-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2400-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2400-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2400-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102201	02/10/1998	

STANDARDIZED BERMUDA GRASS POLLEN

standardized bermuda grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2270
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON POLLEN - UNII:175F461W10)	CYNODON DACTYLON POLLEN	10000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2270-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2270-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2270-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2270-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102195	02/10/1998	

STANDARDIZED ORCHARD GRASS POLLEN

standardized orchard grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2345
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2345-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2345-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2345-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2345-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102198	02/10/1998	

STANDARDIZED PERENNIAL RYE GRASS POLLEN

standardized perennial rye grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2389
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOLIUM PERENNE POLLEN (UNII: 4T81LB52R0) (LOLIUM PERENNE POLLEN - UNII:4T81LB52R0)	LOLIUM PERENNE POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36987-2389-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2389-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2389-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2389-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102200	02/10/1998	

STANDARDIZED TIMOTHY GRASS POLLEN

standardized timothy grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2401
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE POLLEN - UNII:65M88RW2EG)	PHLEUM PRATENSE POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2401-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2401-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2401-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2401-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102202	02/10/1998	

STANDARDIZED REDTOP GRASS POLLEN

standardized redtop grass pollen injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2363
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AGROSTIS GIGANTEA POLLEN (UNII: HU8V6E7HOA) (AGROSTIS GIGANTEA POLLEN - UNII:HU8V6E7HOA)	AGROSTIS GIGANTEA POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2363-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2363-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2363-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2363-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102192	02/10/1998	

STANDARDIZED KENTUCKY (JUNE) BLUEGRASS POLLEN

standardized kentucky (june) bluegrass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2427
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36987-2427-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2427-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2427-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2427-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102196	02/10/1998	

STANDARDIZED MEADOW FESCUE GRASS POLLEN

standardized meadow fescue grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2319
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FESTUCA PRATENSIS POLLEN (UNII: A0WFQ8P6N1) (FESTUCA PRATENSIS POLLEN - UNII:A0WFQ8P6N1)	FESTUCA PRATENSIS POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36987-2319-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2319-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2319-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2319-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102197	02/10/1998	

STANDARDIZED SWEET VERNAL GRASS POLLEN

standardized sweet vernal grass pollen injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:36987-2399
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	100000 [BAU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PHENOL (UNII: 339NCG44TV)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2399-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2399-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2399-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2399-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102201	02/10/1998	

Labeler - Nelco Laboratories, Inc. (054980867)

Registrant - Nelco Laboratories, Inc. (054980867)

Establishment

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

Revised: 11/2009 Nelco Laboratories, Inc.