ASPERGILLUS FUMIGATUS - aspergillus fumigatus injection, solution ALTERNARIA ALTERNATA - alternaria alternata injection, solution ASPERGILLUS FLAVUS - aspergillus flavus injection, solution ASPERGILLUS REPENS - aspergillus repens injection, solution ASPERGILLUS NIGER - aspergillus niger injection, solution ASPERGILLUS TERREUS - aspergillus terreus injection, solution **BOTRYTIS CINEREA** - botrytis cinerea injection, solution **CANDIDA ALBICANS - candida albicans injection, solution** ACREMONIUM STRICTUM - acremonium strictum injection, solution TRICHOTHECIUM ROSEUM - trichothecium roseum injection, solution CLADOSPORIUM CLADOSPORIOIDES - cladosporium cladosporioides injection, solution CHAETOMIUM GLOBOSUM - chaetomium globosum injection, solution **EPICOCCUM NIGRUM - epicoccum nigrum injection, solution** GEOTRICHUM CANDIDUM - geotrichum candidum injection, solution **BIPOLARIS SOROKINIANA** - bipolaris sorokiniana injection, solution **MUCOR PLUMBEUS - mucor plumbeus injection, solution NEUROSPORA INTERMEDIA** - neurospora intermedia injection, solution PENICILIUM CHRYSOGENUM - penicilium chrysogenum injection, solution PENICILLIUM NOTATUM - penicillium notatum injection, solution AUREOBASIDIUM PULLULANS - aureobasidium pullulans injection, solution **RHIZOPUS ORYZAE - rhizopus oryzae injection, solution** RHODOTORULA MUCILAGINOSA - rhodotorula mucilaginosa injection, solution SACCHAROMYCES CEREVISIAE - saccharomyces cerevisiae injection, solution STEMPHYLIUM SARCINIFORMS - stemphylium sarciniforms injection, solution **TRICHODERMA HARZIANAM - trichoderma harzianam injection, solution TRICHOPHYTON MENTAGROPHYTES** - trichophyton mentagrophytes injection, solution CORN SMUT - corn smut injection, solution OAT SMUT - oat smut injection, solution WHEAT SMUT - wheat smut injection, solution WHEAT BUNT - wheat bunt injection, solution WHEAT STEM RUST - wheat stem rust injection, solution **CURVULARIA INEQUALIS - curvularia inequalis injection, solution** FUSARIUM COMPACTUM - fusarium compactum injection, solution PHOMA GLOMERATA - phoma glomerata 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 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 abser + erythema pro than 3 mm d	
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.		
		Any larger reaction with itch		

Four Plus ++++	and pain, and possible diffuse blush of the skin surrounding the reaction area.
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Therapeutic Use: Recommended dosage & range

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

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

SUGGESTED DOSAGE SCHEDULE

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

STRENGTH	DOSE	VOLUME
Vial #1	1	0.05
1:100,000 w/v	2	0.10
10 pnu/ml	3	0.15
1 AU/ml	4	0.20
1 BAU/ml	5	0.30
	6	0.40
	7	0.50
Vial #2	8	0.05
1:10,000 w/v	9	0.10
100 pnu/ml	10	0.15
10 AU/ml	11	0.20
10 BAU/ml	12	0.30
	13	0.40
	14	0.50
Vial #3	15	0.05
1:1,000 w/v	16	0.10
1,000 pnu/ml	17	0.15
100 AU/ml	18	0.20
100 BAU/ml	19	0.30
	20	0.40
	21	0.50
Vial #4	22	0.05
1:100 w/v	23	0.07

10,000 pnu/ml	24	0.10
1,000 AU/ml	25	0.15
1,000 BAU/ml	26	0.20
	27	0.25
Maintenance Refill	28	0.25
1:100 w/v	29	0.25
10,000 pnu/ml	30	0.25
1,000 AU/ml	31	0.25
1,000 BAU/ml	32	0.25
subsequent doses	33	0.25

Preparation Instructions:

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

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

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

Vd x Cd = Vn x Ca

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

0.1 ml = Vn

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

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

10ml x 100 = Vn x 10,000

0.1 ml = Vn

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

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

10ml x 100 = Vn x 10,000

0.1 ml = Vn

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

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

1. PRESEASONAL

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

2. CO-SEASONAL

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

3. PERENNIAL

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

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

HOW SUPPLIED

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

Sizes:

Diagnostic Scratch: 5 ml dropper application vials

Diagnostic Intradermal: 5 ml or 10 ml vials.

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

STORAGE

The expiration date of allergen extracts is listed on the container label. Store extracts upon arrival at 2° to 8°C and keep them in this range during office use.

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

REFERENCES

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

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

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5. Murray, A.B., Ferguson, A., Morrison, B., The frequency and severity of cat allergy vs dog allergy in atopic children. J. Allergy Clin. Immunolo: 72, 145-9, 1985.

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CONTAINER LABELING







CC. Sterile multiple dose vial U.S. Govt. Lic. No. 459 ALLEGGENIC EXTRACT FOR INTRADERMAL TESTING Lot No. ... CC. + or -3.°C. Lot BROOK AVE. DEER PARK. N.Y. 11729

ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information

Product T ype	HUMAN PRESCRIPTION DRUG	Item Code (Source)
Route of Administration	INTRADERMAL, SUBCUTANEOUS	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)	ASPERGILLUS FUMIGATUS	10000 [PNU] in 1 mL
Inactive Ingredients		
Ingredient Name		Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
WATER (UNII: 059QF0KO0R)		
PHENOL (UNII: 339NCG44TV)		

NDC:36987-1848

Packaging								
Item Code	Package Description	Marketing Start Date	Marketing End Date					
NDC:36987-1848-1	5 mL in 1 VIAL, MULTI-DOSE							
NDC:36987-1848-2	10 mL in 1 VIAL, MULTI-DOSE							
NDC:36987-1848-3	30 mL in 1 VIAL, MULTI-DOSE							
NDC:36987-1848-4	50 mL in 1 VIAL, MULTI-DOSE							
	Item Code NDC:36987-1848-1 NDC:36987-1848-2 NDC:36987-1848-3	Item CodePackage DescriptionNDC:36987-1848-15 mL in 1 VIAL, MULTI-DOSENDC:36987-1848-210 mL in 1 VIAL, MULTI-DOSENDC:36987-1848-330 mL in 1 VIAL, MULTI-DOSE	Item CodePackage DescriptionMarketing Start DateNDC:36987-1848-15 mL in 1 VIAL, MULTI-DOSENDC:36987-1848-210 mL in 1 VIAL, MULTI-DOSENDC:36987-1848-330 mL in 1 VIAL, MULTI-DOSE					

Marketing Category	Application	on Number or Monograph Citati	on M	Iarke	ting Start D	ate	Mai	rketing End Dat
BLA	BLA102192		08	/29/19	972			-
ALTERNARIA Ilternaria alternata inj								
Product Informati	on							
Product Type		HUMAN PRESCRIPTION DRUG		Ite m	Code (Sou	ce)	N	NDC:36987-1857
Route of Administrat	ion	INTRADERMAL, SUBCUTANEOUS	S					
Active Ingredient/	Active Moi	etv						
		edient Name			Basis of S	tren	gth	Strength
ALTERNARIA ALTERN UNII:52B29REC7H)	•	B29REC7H) (ALTERNARIA ALTERN	IATA -		ALTERNARL ALTERNATA	A		10000 [PNU] in 1 mL
Inactive Ingredier sodium Chloride (1 sodium Bicarbona	JNII: 451W47IQ FE (UNII: 8MDI							Strength
WATER (UNII: 059QF01 PHENOL (UNII: 339NC0								
Dechaging								
Packaging # Item Code	Pa	ckage Description M	arketing	o Sta	rt Date	М	[arke	ting End Date
1 NDC:36987-1857-1		VIAL, MULTI-DOSE	ui ne tinț	5 0 10	III Dutt	141	uine	ting Life Dute
2 NDC:36987-1857-2		VIAL, MULTI-DOSE						
B NDC:36987-1857-3		VIAL, MULTI-DOSE						
4 NDC:36987-1857-4	50 mL in 1	VIAL, MULTI-DOSE						
Marketing Info	rmation							
Marketing Category	Applicatio	on Number or Monograph Citati	on M	Iarke	ting Start D	ate	Mai	rketing End Dat
				/29/19				

aspergillus flavus injection, solution

Product Information

Product T ype		HUMAN PRESCRIPTION DR	UG	Item	Code (Source	•)	NDC:36987-1866
				Ite II		.)	1120.30307 1000
Route of Administrati	on	SUBCUTANEOUS, INTRAD	ERMAL				
Active Ingredient/	Active Moi	ety					
	Ingr	edient Name			Basis of Stre	ength	Strength
SPERGILLUS FLAVUS INII:3J888Y9L13)	5 (UNII: 3J888	Y9L13) (ASPERGILLUS FLAV	'US -		ASPERGILLUS FLAVUS		10000 [PNU] in 1 mL
nactive Ingredien	ts						
		Ingredient Name					Strength
O DIUM BICARBONAT	TE (UNII: 8 MDI	F5V39QO)					
ODIUM CHLORIDE (U	NII: 451W47IQ	8X)					
VATER (UNII: 059QF0K	(00R)						
HENOL (UNII: 339NCG	44TV)						
Packaging							
Item Code	Pa	ckage Description	Market	ting St	art Date	Mark	eting End Date
NDC:36987-1866-1	5 mL in 1 V	VIAL, MULTI-DOSE					
NDC:36987-1866-2	10 mL in 1	VIAL, MULTI-DOSE					
NDC:36987-1866-3	30 mL in 1	VIAL, MULTI-DOSE					
NDC:36987-1866-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Info	rmation						
Marketing Category	Applicati	on Number or Monograph	Citation	Mark	eting Start Dat	te M	arketing End Date
SLA	BLA102192			08/29/1	972		
SPERGILLUS	REPENS	5					
spergillus repens inje	ction, solutio	on					
Product Informati	on						
Product Information	on	HUMAN PRESCRIPTION DRI	UG	Ite n	n Code (Source	2)	NDC:36987-1875
		HUMAN PRESCRIPTION DRUSUBCUTANEOUS, INTRAD		Ite n	1 Code (Source	2)	NDC:36987-1875
SPERGILLUS	ction, solutio						

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
EUROTIUM HERBARIORUM (UNII: 49W168AES4) (EUROTIUM HERBARIORUM - UNII:49W168AES4)	EUROTIUM HERBARIORUM	10000 [PNU] in 1 mL

Inactive Ingredients

		Ingredient Name				Strength
soi	DIUM CHLORIDE (U	NII: 451W47IQ8X)				
soi	DIUM BICARBONAT	E (UNII: 8 MDF5V39QO)				
WA	TER (UNII: 059QF0K	00R)				
PHE	ENOL (UNII: 339NCG	44TV)				
Pa	ckaging					
#	Item Code	Package Description	Marke	ting Start Date	Μ	arketing End Date
1 N	DC:36987-1875-1	5 mL in 1 VIAL, MULTI-DOSE				
2 N	DC:36987-1875-2	10 mL in 1 VIAL, MULTI-DOSE				
3 N	DC:36987-1875-3	30 mL in 1 VIAL, MULTI-DOSE				
4 N	DC:36987-1875-4	50 mL in 1 VIAL, MULTI-DOSE				
M	arketing Info	rmation				
	rketing Category	Application Number or Monograph	Citation	Marketing Start Da	ate	Marketing End Date
BLA	A	BLA102192		08/29/1972		

ASPERGILLUS NIGER

aspergillus niger injection, solution

Product Information				
	Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1884
	Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ASPERGILLUS NIGER VAR. NIGER (UNII: 910A40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:910A40ANG6)	ASPERGILLUS NIGER VAR. NIGER	10000 [PNU] in 1 mL			

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-1884-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-1884-2	10 mL in 1 VIAL, MULTI-DOSE		

3 NDC:36987-1884-3	30 mL in 1 VIAL, MULTI-DOSE		
4 NDC:36987-1884-4	50 mL in 1 VIAL, MULTI-DOSE		
7 7 7 7 7 7 7			
Marketing Info	rmation		
Marketing Info	rmation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
0		Marketing Start Date 08/29/1972	Marketing End Date

ASPERGILLUS TERREUS

aspergillus terreus injection, solution

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1893	
Route of Administration	INTRADERMAL, SUBCUTANEOUS			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII: QBN8K7055X)	ASPERGILLUS TERREUS	10000 [PNU] in 1 mL			

Inactive Ingredients				
Ingredient Name	Strength			
SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
PHENOL (UNII: 339NCG44TV)				
WATER (UNII: 059QF0KO0R)				

P	ackaging				
#	Item Code	Package Description	Marke	ting Start Date	Marketing End Date
1	NDC:36987-1893-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-1893-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-1893-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-1893-4	50 mL in 1 VIAL, MULTI-DOSE			
N	Iarketing Infor	rmation			
N	Aarketing Category	Application Number or Monograph Ci	tation	Marketing Start Date	Marketing End Date
				08/29/1972	

BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information	on					
Product Type		HUMAN PRESCRIPTION DRU	UG I	Item Code (Sour	rce)	NDC:36987-1902
Route of Administration	on	SUBCUTANEOUS, INTRADI	ERMAL			
Active Ingredient/A	Active Moi	ety				
	Ingr	edient Name		Basis of St	rength	Strength
BOTRYTIS CINEREA (U	JNII: TBW5331	3S7) (BOTRYTIS CINEREA - U	JNII:TBW533135	57) BOTRYTIS C	INEREA	10000 [PNU] in 1 mL
Inactive Ingredien	ts					
		Ingredient Name				Strength
SODIUM BICARBONAT						
SODIUM CHLORIDE (U	-	8X)				
PHENOL (UNII: 339NCG						
	,					
Packaging # Item Code	Pac	ckage Description	Marketing	g Start Date	Mar	keting End Date
Harmonic Packaging # Item Code 1 NDC:36987-1902-1	Pac 5 mL in 1 V	VIAL, MULTI-DOSE	Marketing	g Start Date	Mar	keting End Date
Packaging Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2	Pac 5 mL in 1 V 10 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketing	g Start Date	Mar	keting End Date
Particular Sector Sect	Pac 5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketing	g Start Date	Mar	keting End Date
 WATER (UNII: 059QF0K P=ckaging Item Code NDC:36987-1902-1 NDC:36987-1902-2 NDC:36987-1902-3 NDC:36987-1902-3 	Pac 5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketing	g Start Date	Mar	keting End Date
P-ckaging I Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4	Pac 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				
Packaging # Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4	Pac 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation M	arketing Start I		
Packaging # Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4	Pac 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 M			
Packaging # Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4	Pac 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation M	arketing Start I		
Packaging I Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4 Marketing Information Info	Pac 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 Fmation Application BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation M	arketing Start I		
Packaging # Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4 Marketing Info BLA CANDIDA ALB	Pad 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation M	arketing Start I		
P-ckaging I Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4	Pad 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation M	arketing Start I		
Packaging # Item Code 1 NDC:36987-1902-1 2 NDC:36987-1902-2 3 NDC:36987-1902-3 4 NDC:36987-1902-4 Marketing Info BLA CANDIDA ALB	Pad 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 BLA102192 ICANS tion, solution	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation M	arketing Start I		keting End Date

Route of Administration	SUBCUTANEOUS, INTRADERMAL		
Active Ingredient/Active Moi	ety		
Ingr	edient Name	Basis of Strength	Strength
CANDIDA ALBICANS (UNII: 4D7G21HI UNII:4D7G21HDBC)	OBC) (CANDIDA ALBICANS -	CANDIDA ALBICANS	10000 [PNU] in 1 mL

	Strength			
SODIUM CHLORIDE (U	NII: 451W47IQ8X)			
SODIUM BICARBONAT	E (UNII: 8MDF5V39QO)			
PHENOL (UNII: 339NCG	44TV)			
WATER (UNII: 059QF0K	O0R)			
Packaging				
# Item Code	Package Description	Marke	ting Start Date	Marketing End Date
NDC:36987-1911-1	5 mL in 1 VIAL, MULTI-DOSE			
2 NDC:36987-1911-2	10 mL in 1 VIAL, MULTI-DOSE			
3 NDC:36987-1911-3	30 mL in 1 VIAL, MULTI-DOSE			
4 NDC:36987-1911-4	50 mL in 1 VIAL, MULTI-DOSE			
Marketing Info	rmation			
Marketing Category	Application Number or Monograph	Citation	Marketing Start Da	te Marketing End Date
BLA	BLA102192		08/29/1972	

ACREMONIUM S	STRICT	UM				
acremonium strictum inj	jection, sol	ution				
Product Information	ı					
Product Type		HUMAN PRESCRIPTION DR	UG It	tem Code (Sourc	e) N	NDC:36987-1920
Route of Administration	1	INTRADERMAL, SUBCUTA	NEOUS			
A T 1						
Active Ingredient/A						
	Ingre	edient Name		Basis of St	rength	Strength
ACREMONIUM STRICTUM (UNII: 3F36 V0451W) (ACREMONIUM STRICTUM - ACREMONIUM STRICTUM - STRICTUM			1	10000 [PNU]		
ACREMONIUM STRICTU UNII:3F36V0451W)	M (UNII: 3F36	5 VU451W) (ACREMONIUM S	I RIC I UM -	STRICTUM	1	in 1 mL
	M (UNII: 3F36	VU451W) (ACREMONIUM S	I RIC I UM -		Ĩ	
UNII:3F36V0451W)		5 VU451W) (ACREMONIUM S	TRICTOM -		1	
		5 VU451W) (ACREMONIUM S	TRICTOM -			
UNII:3F36V0451W)		Ingredient Name	TRICTOM -			
UNII:3F36V0451W)		Ingredient Name	TRICTOM -			in 1 mL
UNII:3F36V0451W) Inactive Ingredients	II: 451W47IQ8	Ingredient Name	TRICTOM -			in 1 mL
UNII:3F36V0451W) Inactive Ingredients SODIUM CHLORIDE (UNI	II: 451W47IQ8 (UNII: 8 MDF	Ingredient Name	TRICTOM -			in 1 mL
UNII:3F36V0451W) Inactive Ingredients SODIUM CHLORIDE (UNI SODIUM BICARBONATE	II: 451W47IQ8 (UNII: 8 MDF ITV)	Ingredient Name	TRICTOM -			in 1 mL
UNII:3F36V0451W) Inactive Ingredients SODIUM CHLORIDE (UNI SODIUM BICARBONATE PHENOL (UNII: 339NCG44	II: 451W47IQ8 (UNII: 8 MDF ITV)	Ingredient Name	TRICTOM -			in 1 mL
UNII:3F36V0451W) Inactive Ingredients SODIUM CHLORIDE (UNI SODIUM BICARBONATE PHENOL (UNII: 339NCG44	II: 451W47IQ8 (UNII: 8 MDF ITV)	Ingredient Name	TRICTOM -			in 1 mL
UNII:3F36V0451W) Inactive Ingredients SODIUM CHLORIDE (UNI SODIUM BICARBONATE PHENOL (UNII: 339NCG44	II: 451W47IQ8 (UNII: 8 MDF ITV)	Ingredient Name				in 1 mL
UNII:3F36V0451W) Inactive Ingredients SODIUM CHLORIDE (UNI SODIUM BICARBONATE PHENOL (UNII: 339NCG44 WATER (UNII: 059QF0KO	II: 451W47IQ8 (UNII: 8 MDF (TV) 0 R)	Ingredient Name	Marketing	STRICTUM		in 1 mL

	Marketing Inform Marketing Category	mation Application Number or Monograph Cita	ation Marketi	ng Start Date	Marketing End Date
N	Marketing Inform	mation			
4	NDC:36987-1920-4	50 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-1920-3	30 mL in 1 VIAL, MULTI-DOSE			
		,			

TRICHOTHECIUM ROSEUM

trichothecium roseum injection, solution

Product Information						
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1929			
Route of Administration	SUBCUTANEOUS, INTRADERMAL					

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TRICHO THECIUM ROSEUM (UNII: TGO054E310) (TRICHO THECIUM ROSUNII: TGO054E310)	SEUM - TRICHOTHECIUM ROSEUM	10000 [PNU] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-1929-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-1929-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-1929-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-1929-4	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	

CLADOSPORIUM CLADOSPORIOIDES

Product Informatio	n							
Product T ype		HUMAN PRESCRIPTION DRU	JG	Item	Code (Sourc	e)	NDC:	36987-1938
Route of Administratio	n	SUBCUTANEOUS, INTRADE	ERMAL					
Active Ingredient/A	ctive Moi	ety						
	Ingi	redient Name			Basis of S	Streng	gth	Strength
CLADO SPO RIUM CLAD CLADOSPORIOIDES - UN		ES (UNII: 4ZWY20GTGO) (CL GO)	ADO S PO RIUI		CLADOSPOR CLADOSPOR		5	10000 [PNU] in 1 mL
Inactive Ingredient	5							
		Ingredient Name					S	trength
SODIUM CHLORIDE (UN								
SO DIUM BICARBO NATI	,	75V39QO)						
PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0KC								
Packaging								
# Item Code	Pa	ckage Description	Marketi	ng Sta	rt Date	Mar	keting	g End Date
NDC:36987-1938-1	5 mL in 1 V	VIAL, MULTI-DOSE						
2 NDC:36987-1938-2	10 mL in 1	VIAL, MULTI-DOSE						
B NDC:36987-1938-3	30 mL in 1	VIAL, MULTI-DOSE						
4 NDC:36987-1938-4	50 mL in 1	VIAL, MULTI-DOSE						
	.•							
Marketing Infor	mation							ting End Dat
•		on Number or Monograph	Citation	Market	ting Start Da	te N	farket	
Marketing Category		on Number or Monograph		Marke 8/29/19	ting Start Da 72	te M	farket	
Marketing Infor Marketing Category BLA	Applicatio	on Number or Monograph			-	te M	farke (
Marketing Category	Applicatio BLA102192				-	te M	farket	
Marketing Category BLA	Applicatio BLA102192 GLOBC	SUM			-	te M	farke t	
Marketing Category BLA	Applicatio BLA102192 GLOBO injection, s	SUM			-	te M	larket	
Marketing Category BLA CHAETOMIUM haetomium globosum	Applicatio BLA102192 GLOBO injection, s	SUM	0	8/29/19	-			:36987-1947

Ingredient NameBasis of StrengthStrengthCHAETOMIUM GLOBOSUM (UNII: 50 16 WB8 B8A) (CHAETOMIUM GLOBOSUM-
UNII: 50 16 WB8 B8A)CHAETOMIUM GLOBOSUM-
GLOBOSUM10000 [PNU]
in 1 mL

Ina	ctive Ingredien	ts		
		Ingredient Name		Strength
sol	DIUM CHLORIDE (U	NII: 451W47IQ8X)		
sol	DIUM BICARBONAT	E (UNII: 8MDF5V39QO)		
PHE	E NOL (UNII: 339NCG	44TV)		
WA	TER (UNII: 059QF0K	(00R)		
Pa	ckaging			
		Package Description	Marketing Start Date	Marketing End Date
#	ckaging		Marketing Start Date	Marketing End Date
# 1 N	ckaging Item Code	Package Description	Marketing Start Date	Marketing End Date
#1N2N	ckaging Item Code IDC:36987-1947-1	Package Description 5 mL in 1 VIAL, MULTI-DOSE	Marketing Start Date	Marketing End Date

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

	EPICOCCUM NIGRUM
- 8	

epicoccum nigrum injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1965
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Basis of Strength	Strength
EPICOCCUM NIGRUM	10000 [PNU] in 1 m
	Strength
	EPICOCCUM

NDC	m Code	Pa	ckage Description	Marketin	ig Stai	rt Date	Marke	ting End Date
NDC:369	87-1965-1	5 mL in 1 V	'IAL, MULTI-DOSE					
NDC:369	87-1965-3	30 mL in 1	VIAL, MULTI-DOSE					
NDC:369	87-1965-4	50 mL in 1	VIAL, MULTI-DOSE					
NDC:369	87-1965-2	10 mL in 1	VIAL, MULTI-DOSE					
Market	ting Infor	mation						
	g Category		on Number or Monograph	h Citation N	Jarket	ing Start D	ate Ma	rketing End Da
BLA		BLA102192	on number of Monograph		3/29/19	-		i kë ting Liiti Da
		DERIO2152			5725715	/ 2		
GEOTR	RICHUM	CANDII	DUM					
geotrichum	n candidum i	injection, so	lution					
Product	Informatio	n						
Product T	ype		HUMAN PRESCRIPTION DE	RUG	Ite m O	Code (Sour	rce) I	NDC:36987-1983
Route of A	dministratio	n	SUBCUTANEOUS, INTRAI	DERMAL				
Active In	gredient/A	Active Moi	ety					
		Ingr	edient Name			Basis of S	trength	Strength
GEOTRICH UNII:5964J7		U M (UNII: 596	4J742O8) (GEOTRICHUM C	ANDIDUM -		EOTRICHUN ANDIDUM	M	10000 [PNU] in 1 mL
0111.000407	4200)							
Inactive	Ingredient	S						
	0		Ingredient Name					Strength
	HLORIDE (UI	NII: 451W47IQ	0					U U
SODIUM CI								
	ICARBONAT	E (UNII: 8 MDF	5V39QO)					
SO DIUM BI	ICARBONAT JNII: 339NCG4		5V39QO)					
SODIUM BI PHENOL (U		44TV)	5V39QO)					
SODIUMB) PHENOL (U WATER (U)	JNII: 339NCG4 NII: 059QF0K(44TV)	5V39QO)					
so dium Bi phenol (U water (Uf Packagin	JNII: 339NCG4 NII: 059QF0K(44TV) DOR)	5V39QO) Skage Description	Marketin	ıg Stai	rt Date	Marke	ting End Date
SODIUMBI PHENOL (U WATER (UP Packagin # Ite	JNII: 339NCG4 NII: 059QF0K0 ng em Code	44TV) DOR) Pae		Marketin	ıg Stai	rt Date	Marke	ting End Date
SODIUMB) PHENOL (U WATER (UP Packagin # Ite 1 NDC:369	JNII: 339NCG4 NII: 059QF0K0 1g 2 m Code 87-1983-1	14TV) DOR) Pae 5 mL in 1 V	ckage Description	Marketin	ıg Stai	rt Date	Marke	ting End Date
SO DIUM BI PHENOL (U WATER (UN Packagin # Ite 1 NDC:369 2 NDC:369	JNII: 339NCG4 NII: 059QF0K 19 19 19 19 19 19 19 19 19 19 19 19 19	14TV) 20 R) Pac 5 mL in 1 V 10 mL in 1	r kage Description TAL, MULTI-DOSE	Marketin	ıg Stai	rt Date	Marke	ting End Date
SODIUM BI PHENOL (U WATER (UN BERNER	JNII: 339 NCG4 NII: 059 QF0 K0 ng m Code 87-1983-1 87-1983-2 87-1983-3	44TV) 20 R 5 mL in 1 V 5 mL in 1 V 10 mL in 1 30 mL in 1	E kage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	ıg Staı	rt Date	Marke	ting End Date
SODIUM BI PHENOL (U WATER (UN BUDC:369 2 NDC:369 3 NDC:369	JNII: 339 NCG4 NII: 059 QF0 K0 ng m Code 87-1983-1 87-1983-2 87-1983-3	44TV) 20 R 5 mL in 1 V 5 mL in 1 V 10 mL in 1 30 mL in 1	S kage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	ıg Stai	rt Date	Marke	ting End Date
SO JIUM B) PHENOL (U WATER (UN # Ite 1 NDC:369 2 NDC:369 3 NDC:369 4 NDC:369	JNII: 339 NCG4 NII: 059 QF0 K0 ng m Code 87-1983-1 87-1983-2 87-1983-3	44TV) DOR) DOR 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	S kage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	ıg Staı	rt Date	Marke	ting End Date
SO JIUM BI PHENOL (U WATER (UN # Ite 1 NDC:369 3 NDC:369 4 NDC:369 4 NDC:369	JNII: 339 NCG4 NII: 059 QF0 K0 m Code 87-1983-1 87-1983-2 87-1983-3 87-1983-4	14TV) OOR) OR 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	S kage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			rt Date ing Start D		ting End Date

ipomito oo		ijection, soli						
Product I	nformatio	n						
Product Ty	'p e		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sour	ce)	NDC:36987-1992
Route of Ac	lministratio	n	SUBCUTANEOUS, INTRAE	DERMAL				
Active Ing	gredient/A	Active Moi	ety					
		Ingr	edient Name			Basis of S	Strength	Strength
COCHLIOB UNII:3LN5B7		VUS (UNII: 3L	N5B70U4W) (COCHLIOBOL	US SATIVUS -		COCHLIOBO SATIVUS	OLUS	10000 [PNU] in 1 mL
Inactive I	ngredient	S						
			Ingredient Name					Strength
SO DIUM CH	LORIDE (U	NII: 451W47IQ	3X)					
		NII: 451W47IQ E (UNII: 8MDF						
SO DIUM BI	CARBONAT	E (UNII: 8 MDF						
SODIUM BIO PHENOL (U	C ARBONAT NII: 339NCG4	E (UNII: 8 MDF 14TV)						
SODIUM BIO PHENOL (U	C ARBONAT NII: 339NCG4	E (UNII: 8 MDF 14TV)						
SODIUM BIO PHENOL (UI WATER (UN	C ARBONAT NII: 339NCG4 II: 059QF0K	E (UNII: 8 MDF 14TV)						
SODIUM BIG PHENOL (UI WATER (UN Packaging	C ARBONAT NII: 339NCG4 II: 059QF0K4	E (UNII: 8 MDF 14TV) D0R)	5V39QO)					
SO DIUM BIO PHENOL (UI WATER (UN Packaging # Iter	CARBONAT NII: 339NCG4 II: 059QF0K g n Code	E (UNII: 8MDF 14TV) DOR) Pac	5V39QO) ckage Description	Marketi	ng Sta	nrt Date	Marke	eting End Date
SODIUM BIG PHENOL (U) WATER (UN) Packaging # Iter 1 NDC:3698	CARBONAT NII: 339NCG4 II: 059QF0K g n Code 7-1992-1	E (UNII: 8 MDF 14TV) D0R) 5 mL in 1 V	5V39QO) S kage Description TAL, MULTI-DOSE	Marketi	ng Sta	nrt Date	Marke	eting End Date
SODIUM BIG PHENOL (U) WATER (UN) Packaging # Iter 1 NDC:3698	CARBONAT NII: 339NCG4 II: 059QF0K g n Code 7-1992-1	E (UNII: 8 MDF 14TV) D0R) 5 mL in 1 V	5V39QO) ckage Description	Marketi	ng Sta	urt Date	Marke	eting End Date
SO DIUM BIG PHENOL (UI WATER (UN PECKAGGING I NDC:3698 NDC:3698	CARBONAT NII: 339NCG4 II: 059QF0K4 g n Code 7-1992-1 7-1992-2	E (UNII: 8 MDF 14TV) D0 R) 5 mL in 1 V 10 mL in 1	5V39QO) S kage Description TAL, MULTI-DOSE	Marketi	ng Sta	ırt Date	Marke	eting End Date
SO DIUM BIO PHENOL (UI WATER (UN Packaginą # Iter	CARBONAT NII: 339NCG4 II: 059QF0K4 g n Code 7-1992-1 7-1992-2 7-1992-3	E (UNII: 8 MDF 44TV) 00 R) 5 mL in 1 V 10 mL in 1 30 mL in 1	5V39QO) Skage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	nrt Date	Marke	eting End Date
 SO JIUM BIG PHENOL (UI) WATER (UN) Packaging MDC:3698 NDC:3698 NDC:3698 	CARBONAT NII: 339NCG4 II: 059QF0K4 g n Code 7-1992-1 7-1992-2 7-1992-3	E (UNII: 8 MDF 44TV) 00 R) 5 mL in 1 V 10 mL in 1 30 mL in 1	5V39QO) Ekage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	urt Date	Mark	eting End Date
SO JIUM BIG PHENOL (U) WATER (UN) # Iter 1 NDC:3698 2 NDC:3698 3 NDC:3698	CARBONAT NII: 339NCG4 II: 059QF0K4 g n Code 7-1992-1 7-1992-2 7-1992-3 7-1992-4	E (UNII: 8 MDF 44TV) OOR) 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	5V39QO) Ekage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	art Date	Marke	eting End Date
SO JIUM BIG PHENOL (U) WATER (UN) # Iter 1 NDC:3698 2 NDC:3698 3 NDC:3698	CARBONAT NII: 339 NCG4 II: 059 QF0 K g n Code 7-1992-1 7-1992-2 7-1992-3 7-1992-3 7-1992-4	E (UNII: 8 MDF 44TV) D0 R) 50 R 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	5V39QO) Ekage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			rt Date		
SOUUMBIA PHENOL (U) V→TER (UN) P→Ckaging 1 NDC:3698 3 NDC:3698 4 NDC:3698 4 NDC:3698 4 NDC:3698	CARBONAT NII: 339 NCG4 II: 059 QF0 K g n Code 7-1992-1 7-1992-2 7-1992-3 7-1992-3 7-1992-4	E (UNII: 8 MDF 44TV) D0 R) 50 R 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	5V39QO) Exage Description TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation		ting Start D		eting End Date

mucor plumbeus injection, solutior	1		
Product Information			
Product T ype	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2001
Route of Administration	SUBCUTANEOUS, INTRADERMAL		
Active Ingredient/Active Moi	ety		
Ingr	edient Name	Basis of Strength	Strength

MUCOR PLUMBEUS (U	NII: D740 1PWY6E) (MUCOR PLUMBEUS - U	JNII:D7401PWY6E)	MUCOR PLUMBEUS	5 10000 [PNU] in 1 mL
Inactive Ingredien	ts			
	Ingredient Name			Strength
SODIUM CHLORIDE (U	INII: 451W47IQ8X)			
SODIUM BICARBONAT	TE (UNII: 8MDF5V39QO)			
PHENOL (UNII: 339NCC	644TV)			
WATER (UNII: 059QF0F	(00R)			
Packaging				
# Item Code	Package Description	Marketing S	tart Date Ma	rketing End Date
1 NDC:36987-2001-1	5 mL in 1 VIAL, MULTI-DOSE			
2 NDC:36987-2001-2	10 mL in 1 VIAL, MULTI-DOSE			
3 NDC:36987-2001-3	30 mL in 1 VIAL, MULTI-DOSE			
4 NDC:36987-2001-4	50 mL in 1 VIAL, MULTI-DOSE			
4 NDC:36987-2001-4	50 mL in 1 VIAL, MULTI-DOSE			
4 NDC:36987-2001-4	50 mL in 1 VIAL, MULTI-DOSE			
4 NDC:36987-2001-4				
	rmation	Citation Marl	ceting Start Date	Marketing End Date

NEUROSPORA INTERMEDIA

neurospora intermedia injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2010
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Ingredient Name	Basis of Strength	Strength
NEUROSPORA INTERMEDIA (UNII: 2072U60DUI) (NEUROSPORA INTERMEDIA - UNII:2072U60DUI)	NEUROS PORA INTERMEDIA	10000 [PNU] in 1 mL
Inactive Ingredients		
Ingredient Name		Strength
SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)		
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)		
PHENOL (UNII: 339NCG44TV)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36987-2010-1	5 mL in 1 VIAL, MULTI-DOSE		
2 NDC:36987-2010-2	10 mL in 1 VIAL, MULTI-DOSE		
3 NDC:36987-2010-3	30 mL in 1 VIAL, MULTI-DOSE		
4 NDC:36987-2010-4	50 mL in 1 VIAL, MULTI-DOSE		
Marketing Info	ormation		
Marketing Category	Application Number or Monograph	Citation Marketing Start Da	te Marketing End Date
BLA	BLA102192	08/29/1972	

		HRYSOGENUM n injection, solution						
Pro	duct Informatio	n						
Proc	luct T ype	HUMAN PRESCRIPTION D	RUG	Ite m	Code (Sour	ce)	NDC:3	6987-2037
Rout	te of Administratio	n SUBCUTANEOUS, INTRA	DERMAL					
Acti	ive Ingredient/A	Active Moiety						
	-	Ingredient Name			Basis of	Stren	gth	Strength
		GENUM VAR. CHRYSOGENUM (UNII: 33 ENUM VAR. CHRYSOGENUM - UNII:331P			PENICILLIUM CHRYSOGENI CHRYSOGENI	UM VAR		10000 [PNU in 1 mL
	t ive Ingredient IUM BICARBONATI	S Ingredient Name E (UNII: 8MDF5V39QO)					Sti	rength
SOD	IUM CHLORIDE (UN	NII: 451W47IQ8X)						
	NOL (UNII: 339NCG4							
WAT	ER (UNII: 059QF0KC	50R)						
Pac	kaging							
#	Item Code	Package Description	Marketii	ng Sta	art Date	Mar	keting	End Date
1 NE	DC:36987-2037-1	5 mL in 1 VIAL, MULTI-DOSE						
2 NE	DC:36987-2037-2	10 mL in 1 VIAL, MULTI-DOSE						
3 NE	DC:36987-2037-3	30 mL in 1 VIAL, MULTI-DOSE						
4 NE	DC:36987-2037-4	50 mL in 1 VIAL, MULTI-DOSE						
Ma	rketing Infor	mation						

08/29/1972

	ection, solution				
Product Information	on				
Product Type	HUMAN PRESCRIPTION	N DRUG	tem Code (Source)	NDC:3	6987-2046
Route of Administrati	on SUBCUTANEOUS, INT	RADERMAL			
Active Ingredient/	Active Moiety				
	Ingredient Name		Basis of Stre	ngth	Strength
	GENUM VAR. CHRYSO GENUM (UNI GENUM VAR. CHRYSO GENUM - UNII:3 ¹		PENICILLIUM CHRYSOGENUM V CHRYSOGENUM	AR.	10000 [PNU in 1 mL
Inactive Ingredien					
	Ingredient Name	!		Sti	rength
SODIUM BICARBONAT					
SODIUM CHLORIDE (U	NII: 451W47IQ8X)				
DIFINOL (UNIL DOONCO					
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K					
WATER (UNII: 059QF0K					
WATER (UNII: 059QF0K					
WATER (UNII: 059QF0K Packaging		Marketing	g Start Date M	arketing	End Date
WATER (UNII: 059QF0K Packaging # Item Code	.00R)	Marketing	s Start Date M	arketing	End Date
WATER (UNII: 059QF0K Packaging # Item Code	Package Description	Marketing	g Start Date M	arketing	End Date
WATER (UNII: 059QF0K Packaging # Item Code 1 NDC:36987-2046-1 2 NDC:36987-2046-2	ADD BACKAGE Description SmL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	Marketing	s Start Date M	arketing	End Date
WATER (UNII: 059QF0K P ckaging # Item Code 1 NDC:36987-2046-1	ADD BY AND	Marketing	g Start Date M	arketing	End Date
 WATER (UNII: 059QF0K P - kaging I tem Code NDC:36987-2046-1 NDC:36987-2046-3 NDC:36987-2046-3 NDC:36987-2046-4 	Package Description 5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE 50 mL in 1 VIAL, MULTI-DOSE	Marketing	s Start Date M	arketing	End Date
 WATER (UNII: 059QF0K P - ckaging I tem Code NDC:36987-2046-1 NDC:36987-2046-3 NDC:36987-2046-3 NDC:36987-2046-4 	Package Description 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		s Start Date M		End Date
Watter (UNII: 059QF0K I <td>Package Description 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 50 mL in 1 VIAL, MULTI-DOSE</td> <td>aph Citation M</td> <td></td> <td></td> <td></td>	Package Description 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 50 mL in 1 VIAL, MULTI-DOSE	aph Citation M			
Watter (UNII: 059QF0K Partial Code I Item Code I NDC:36987-2046-1 I NDC:36987-2046-2 I NDC:36987-2046-3 NDC:36987-2046-4	Package Description 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 50 mL in 1 VIAL, MULTI-DOSE Tmation	aph Citation M	arketing Start Date		

Product Information						
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2064			
Route of Administration	SUBCUTANEOUS, INTRADERMAL					

Active Ingredient/							
	Ingr	edient Name			Basis of	Strength	Strength
		. PULLUTANS (UNII: D1A2N PULLUTANS - UNII:D1A2NG6			AUREOBASIE PULLULANS PULLUTANS		10000 [PNU in 1 mL
Inactive Ingredien	its						
		Ingredient Name				St	rength
SODIUM CHLORIDE (U	JNII: 451W47IQ	3X)					
SODIUM BICARBONAT	Г Е (UNII: 8 MDF	5V39QO)					
PHENOL (UNII: 339NCG	644TV)						
WATER (UNII: 059QF0k	KOOR)						
Packaging							
# Item Code	Pa	ckage Description	Marketi	ng Sta	art Date	Marketing	End Date
1 NDC:36987-2064-1	5 mL in 1 V	IAL, MULTI-DOSE					
2 NDC:36987-2064-2	10 mL in 1	VIAL, MULTI-DOSE					
3 NDC:36987-2064-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC:36987-2064-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Info	rmation						
Marketing Category	Applicatio	on Number or Monograph	Citation	Marke	eting Start Da	ate Marketi	ng End Date
BLA	BLA102192		0	8/29/1	972		
			1			1	
RHIZOPUS OR	YZAE						
rhizopus oryzae injec	tion, solution						
Product Informati	on						
Product T ype		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sourc	ce) NDC:3	86987-2073
Route of Administrati	on	SUBCUTANEOUS, INTRAD	ERMAL				
Active Ingredient/		•					
	•	edient Name			Basis of	_	Strength
RHIZOPUS ARRHIZUS VAR. ARRHIZUS - UNII:8		US (UNII: 8476849N1Y) (RHI	ZOPUS ARRHI	IZUS	RHIZOPUS AF ARRHIZUS	RRHIZUS VAR.	10000 [PNU] in 1 mL
Inactive Ingredien	ite						
macuve mgreulen	11.5	Ingradiant Name				C+	rongth
		Ingredient Name				St	rength
SODIUM CHLORIDE (U							
SODIUM BICARBONAT	TE (UNII: 8 MDF	5V39QO)					

	44TV)					
WATER (UNII: 059QF0K	KO0R)					
Packaging						
# Item Code	Pac	ckage Description	Marketi	ng Start Date	Marl	ceting End Date
1 NDC:36987-2073-1	5 mL in 1 V	'IAL, MULTI-DOSE				
2 NDC:36987-2073-2	10 mL in 1	VIAL, MULTI-DOSE				
3 NDC:36987-2073-3	30 mL in 1	VIAL, MULTI-DOSE				
4 NDC:36987-2073-4	50 mL in 1	VIAL, MULTI-DOSE				
Marketing Info	rmation					
0		NT 1 NF 1	<u></u>			
Marketing Category	Applicatio	on Number or Monograph		Marketing Start Da	ate M	arketing End Date
Marketing Category		on Number or Monograph		Marketing Start Da 8/29/1972	ate M	arketing End Date
Marketing Category	Applicatio	on Number or Monograph		-	ate M	arketing End Date
Marketing Category BLA	Applicatio BLA102192			-	ate M	arketing End Date
Marketing Category BLA RHODOTORUL	Application BLA102192	LAGINOSA		-	ate M	arketing End Date
Marketing Category BLA RHODOTORUL	Application BLA102192	LAGINOSA		-	ate M	arketing End Date
Marketing Category BLA RHODOTORUI	Application BLA102192 LA MUCE osa injection	LAGINOSA		-	ate M	arketing End Date
Marketing Category BLA RHODOTORUL	Application BLA102192 LA MUCE osa injection	LAGINOSA		-	ate M	arketing End Date
Marketing Category BLA RHODOTORUI	Application BLA102192 LA MUCE osa injection	LAGINOSA	C	-		arketing End Date

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
RHODOTORULA MUCILAGINOSA (UNII: 62TY3X4N9Z) (RHODOTORULA MUCILAGINOSA - UNII:62TY3X4N9Z)	RHODOTORULA MUCILAGINOSA	10000 [PNU] in 1 mL

Strength

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36987-2082-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-2082-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-2082-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-2082-4	50 mL in 1 VIAL, MULTI-DOSE			

	Applicatio	on Number or Monograph	Citation	Marke	ting Start Date	Mar	keting End Dat
Marketing Category BLA	BLA102192			08/29/19	-		ne eing Ene Dut
SACCHAROMY	YCES CEI	REVISIAE					
accharomyces cerev	visiae injectio	n, solution					
Product Informati	on						
Product T ype		HUMAN PRESCRIPTION DF	UG	Ite m	Code (Source) N	DC:36987-2091
Route of Administrat	ion	SUBCUTANEOUS, INTRAE	DERMAL				
Active Ingredient/		0					
	0	edient Name			Basis of Str	rength	Strength
SACCHAROMYCES CE CEREVISIAE - UNII:9781	•	II: 978 D8 U4 19 H) (SACCHAR	OMYCES		SACCHAROMY(CEREVISIAE	CES	10000 [PNU] in 1 mL
Inactive Ingredier	its						
		Ingredient Name					Strength
SODIUM CHLORIDE (U							
SODIUM BICARBONA PHENOL (UNII: 339NCC		5739QU)					
WATER (UNII: 059QF01	,						
Packaging							
	Pac	ckage Description	Market	ing Sta	rt Date	Market	ting End Date
1 NDC:36987-2091-1		TAL, MULTI-DOSE					
I NDC:36987-2091-1 Z NDC:36987-2091-2	10 mL in 1	VIAL, MULTI-DOSE					
1 NDC:36987-2091-1 2 NDC:36987-2091-2 3 NDC:36987-2091-3	10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE					
NDC:36987-2091-1 NDC:36987-2091-2 NDC:36987-2091-2 NDC:36987-2091-3	10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE					
1 NDC:36987-2091-1	10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE					
 NDC:36987-2091-1 NDC:36987-2091-2 NDC:36987-2091-3 NDC:36987-2091-3 NDC:36987-2091-4 	10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marke	ting Start Date	e Mar	keting End Dat

STEMPHYLIUM SARCINIFORMS

stemphylium sarciniforms injection, solution

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:36987-2109

Active Ingredient	t/Active Moiety				
	Ingredient Name		Basis of	Strength	Strength
STEMPHYLIUM SARC SARCINIFORME - UNII:	E INIFORME (UNII: XQ14H1462M) (STEMP XQ14H1462M)	HYLIUM	STEMPHYLI SARCINIFO		10000 [PNU] in 1 mL
Inactive Ingredie	nts				
	Ingredient Name				Strength
SODIUM BICARBONA	ATE (UNII: 8 MDF5V39QO)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
PHENOL (UNII: 339 NC	G44TV)				
WATER (UNII: 059QF0	KOOR)				
	KOOR)				
Packaging	KOOR) Package Description	Marketing S	tart Date	Market	ing End Date
Packaging # Item Code		Marketing S	tart Date	Market	ing End Date
Packaging#Item Code1NDC:36987-2109-1	Package Description	Marketing S	tart Date	Market	ing End Date
Figure 1 NDC:36987-2109-1 2 NDC:36987-2109-2	Package Description 5 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Market	ing End Date
Packaging Item Code MDC:36987-2109-1 NDC:36987-2109-2 NDC:36987-2109-3	Package Description 5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Market	ing End Date
	Package Description5 mL in 1 VIAL, MULTI-DOSE10 mL in 1 VIAL, MULTI-DOSE30 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Market	ing End Date
Particular Set	Package Description5 mL in 1 VIAL, MULTI-DOSE10 mL in 1 VIAL, MULTI-DOSE30 mL in 1 VIAL, MULTI-DOSE50 mL in 1 VIAL, MULTI-DOSE	Marketing S	tart Date	Market	ing End Date
Figure 1 Figure 2 Figure 2	Package Description 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		tart Date		ing End Date keting End Dat

TRICHODERMA HARZIANAM

trichoderma harzianam injection, solution

Product Information			
Product T ype	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2118
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TRICHO DERMA HARZIANUM (UNII: CA33Q4013Q) (TRICHO DERMA HARZIANUM - UNII:CA33Q4013Q)	TRICHO DERMA HARZIANUM	10000 [PNU] in 1 mL		
Inactive Ingredients				
Ingredient Name		Strength		

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2127
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Mo	iety		
Ingi	redient Name	Basis of Strength	Strength
TRICHO PHYTO N MENTAGRO PHYT MENTAGROPHYTES - UNII:19917J3JIV	T ES (UNII: 19917J3JIV) (TRICHOPHYTON)	TRICHOPHYTON MENTAGROPHYTES	10000 [PNU] in 1 mL

Inactive Ingredients				
In	gredient Name	Strength		
SODIUM BICARBONATE (UNII: 8 MDF5V39 Q	0)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
PHENOL (UNII: 339NCG44TV)				
WATER (UNII: 059QF0KO0R)				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC	2:36987-2127-1	5 mL in 1 VIAL, MULTI-DOSE		
2 NDC	2:36987-2127-2	10 mL in 1 VIAL, MULTI-DOSE		
3 NDC	2:36987-2127-3	30 mL in 1 VIAL, MULTI-DOSE		

	•						
Marketing Info	ormation						
Marketing Category	Applicatio	on Number or Monograph	Citation	Marke	eting Start D	Date M	Aarketing End Date
BLA	BLA102192		0	8/29/1	972		
CORN SMUT							
orn smut injection,	solution						
Product Informat	ion						
Product Type		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sou	rce)	NDC:36987-2145
Route of Administra	tion	SUBCUTANEOUS, INTRAE	ERMAL				
Active Ingredient	Active Moio	ety					
i i cuive ingi cuiem							
	Ingr	edient Name			Basis of St	rength	Strength
JSTILAGO MAYDIS (UNII: 4K7Z7K7S	edient Name WG) (USTILAGO MAYDIS - 1	JNII:4K7Z7K7S		Basis of St USTILAGO N	-	Strength 10000 [PNU] in 1 m]
USTILAGO MAYDIS (Inactive Ingredie:	UNII: 4K7Z7K7S	WG) (USTILAGO MAYDIS - 1 Ingredient Name	JNII:4K7Z7K7S			-	_
USTILAGO MAYDIS (Inactive Ingredie SODIUM BICARBONA	UNII: 4K7Z7K7S nts TE (UNII: 8MDF	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO)	JNII:4K7Z7K7S			-	10000 [PNU] in 1 mI
USTILAGO MAYDIS (Inactive Ingredie: SODIUM BICARBONA SODIUM CHLORIDE (UNII: 4K7Z7K7S nts TE (UNII: 8 MDF UNII: 451W47IQ8	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO)	JNII:4K7Z7K7S			-	10000 [PNU] in 1 mI
USTILAGO MAYDIS (Inactive Ingredie SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO)	JNII:4K7Z7K7S			-	10000 [PNU] in 1 mI
USTILAGO MAYDIS (Inactive Ingredie SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO)	JNII:4K7Z7K75			-	10000 [PNU] in 1 mI
USTILAGO MAYDIS (Inactive Ingredie SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO)	JNII:4K7Z7K7S			-	10000 [PNU] in 1 mI
USTILAGO MAYDIS (Inactive Ingredie SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO)	JNII:4K7Z7K7S			-	10000 [PNU] in 1 mI
USTILAGO MAYDIS (Inactive Ingredie: SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 Packaging	UNII: 4K7Z7K7S nts TE (UNII: 8 MDF UNII: 451W47IQ8 G44TV) KO0R)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO)	JNII:4K7Z7K7S	SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 mI
USTILAGO MAYDIS (Inactive Ingredie SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 Packaging I tem Code	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV) KO0R) Pac	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X)		SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml
USTILAGO MAYDIS (Inactive Ingredie: SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 Packaging I tem Code NDC:36987-2145-1 NDC:36987-2145-2	UNII: 4K7Z7K7S nts TE (UNII: 8 MDF UNII: 451W47IQ8 G44TV) KO0 R)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X) Ekage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE		SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml
USTILAGO MAYDIS (Inactive Ingredie: SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 WATER (UNII: 059QF0 Packaging I tem Code NDC:36987-2145-1 NDC:36987-2145-3	UNII: 4K7Z7K7S nts TE (UNII: 8 MDF UNII: 451W47IQ8 G44TV) KO0 R) KO0 R) 5 mL in 1 V 10 mL in 1 V 30 mL in 1 V	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X) 3X) Kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE		SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml
USTILAGO MAYDIS (Inactive Ingredie: SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 WATER (UNII: 059QF0 Packaging I tem Code NDC:36987-2145-1 NDC:36987-2145-3	UNII: 4K7Z7K7S nts TE (UNII: 8 MDF UNII: 451W47IQ8 G44TV) KO0 R) KO0 R) 5 mL in 1 V 10 mL in 1 V 30 mL in 1 V	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X) Ekage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE		SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml
USTILAGO MAYDIS (Inactive Ingredies SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 WATER (UNII: 059QF0 Packaging I tem Code NDC:36987-2145-1 NDC:36987-2145-3	UNII: 4K7Z7K7S nts TE (UNII: 8 MDF UNII: 451W47IQ8 G44TV) KO0 R) KO0 R) 5 mL in 1 V 10 mL in 1 V 30 mL in 1 V	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X) 3X) Kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE		SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml
USTILAGO MAYDIS (ININICIPAL CARBONA SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC) WATER (UNII: 059QF0) FIENOL (UNII: 059QF0) MATER (UNII: 059QF0)	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV) KO0R)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X) 3X) Kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE		SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml
USTILAGO MAYDIS (Inactive Ingredie: SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 Filenol (UNII: 059QF0 MATER (UNII: 059QF0	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV) KO0R)	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X) 3X) Kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE		SWG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml
USTILAGO MAYDIS (Inactive Ingredie SODIUM BICARBONA SODIUM CHLORIDE (PHENOL (UNII: 339NC WATER (UNII: 059QF0 Packaging	UNII: 4K7Z7K7S nts TE (UNII: 8MDF UNII: 451W47IQ8 G44TV) KO0 R) 5 mL in 1 V 30 mL in 1 V 50 mL in 1 V 50 mL in 1 V	WG) (USTILAGO MAYDIS - 1 Ingredient Name 5V39QO) 3X) 3X) Kage Description IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	swG)	USTILAGO N	MAYDIS	10000 [PNU] in 1 ml

oat smut injection, solution

Product Information	1					
Product Type		HUMAN PRESCRIPTION D	RUG	Item Code (Sou	ırce)	NDC:36987-2154
Route of Administration	1	SUBCUTANEOUS, INTRA	DERMAL			
Active Ingredient/A	ctive Moie	ty				
	Ingre	dient Name		Basis of St	rength	Strength
USTILAGO AVENAE (UNI	II: YIH315U1T	J) (USTILAGO AVENAE -	UNII:YIH315U1T	U) USTILAGO A	AVENAE	10000 [PNU] in 1 m
Inactive Ingredients	i					
		Ingredient Name				Strength
SO DIUM BICARBO NATE	(UNII: 8 MDF	5V39QO)				
SODIUM CHLORIDE (UNI	II: 451W47IQ8	X)				
PHENOL (UNII: 339NCG44	ITV)					
WATER (UNII: 059QF0KO	0 R)					
Packaging						
# Item Code	Pac	kage Description	Marketi	ng Start Date	Mar	keting End Date
1 NDC:36987-2154-1	5 mL in 1 VI	AL, MULTI-DOSE				
2 NDC:36987-2154-2	10 mL in 1 V	IAL, MULTI-DOSE				
3 NDC:36987-2154-3	30 mL in 1 V	/IAL, MULTI-DOSE				
4 NDC:36987-2154-4		/IAL, MULTI-DOSE				
Marketing Inform						
Marketing Category	Applicatio	n Number or Monograp	h Citation	Marketing Start	Date N	larketing End Dat
BLA E	3LA102192		0	8/29/1972		
WHEAT SMUT						
vheat smut injection, so	olution					
Product Information	1					
Product T ype		HUMAN PRESCRIPTION D	RUG	Item Code (Sou	irce)	NDC:36987-2163
Route of Administration	1	SUBCUTANEOUS, INTRA	DERMAL			
Active Ingredient/A		0				
	0	dient Name		Basis of St	-	Strength
USTILAGO TRITICI (UNI	I: BV820L2IZ	28) (USTILAGO TRITICI - U	JNII:BV82OL2IZ	8) USTILAGO 1	FRITICI	10000 [PNU] in 1 m
Inactive Ingredients						

		Ingredient Name					Strength
SODIUM BICARBONAT	E (UNII: 8 MDF5	5V39QO)					
SODIUM CHLORIDE (UN	NII: 451W47IQ8	X)					
PHENOL (UNII: 339NCG4	44TV)						
WATER (UNII: 059QF0K)	O0R)						
Packaging							
# Item Code	Pac	kage Description	Marke	ting St	art Date	Ma	arketing End Date
1 NDC:36987-2163-1	5 mL in 1 VI	AL, MULTI-DOSE					
2 NDC:36987-2163-2	10 mL in 1 V	IAL, MULTI-DOSE					
3 NDC:36987-2163-3		/IAL, MULTI-DOSE					
4 NDC:36987-2163-4	50 mL in 1 V	/IAL, MULTI-DOSE					
Marketing Infor	mation						
U		Number	h Circuit	N.F. 7			Markether
Marketing Category	Application BLA102192	n Number or Monograp	n Citation		eting Start I	Jate	Marketing End Date
BLA	BLA102192			08/29/1	972		
WHEAT BUNT							
wheat bunt injection, so							
wheat bunt injection, so				_			
wheat bunt injection, so Product Informatio	n	HUMAN PRESCRIPTION D	PRUG	Iten	1 Code (Sou	rce)	NDC:36987-2172
	n	HUMAN PRESCRIPTION D INTRADERMAL, SUBCUT		Iten	ı Code (Sou	rce)	NDC:36987-2172
wheat bunt injection, so Product Informatio Product Type Route of Administratio	on On	INTRADERMAL, SUBCUT		Iten	ı Code (Sou	rce)	NDC:36987-2172
wheat bunt injection, so Product Informatio Product Type Route of Administratio	on on Active Moie	INTRADERMAL, SUBCUT					
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient/A	on on Active Moie Ingrec	INTRADERMAL, SUBCUT	ANEOUS		ı Code (Sou Basis of Str TLLETIA CAF	rength	
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient /A TILLETIA CARIES (UNII	on Active Moie Ingrec E C7000B9PQI	INTRADERMAL, SUBCUT ty lient Name	ANEOUS		Basis of Str	rength	Strength
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient /A TILLETIA CARIES (UNII	on Active Moie Ingrec E C7000B9PQI	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI	ANEOUS		Basis of Str	rength	Strength 10000 [PNU] in 1 m]
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient /A TILLETIA CARIES (UNII Inactive Ingredient	on Active Moie Ingrec :: C7000B9PQI	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name	ANEOUS		Basis of Str	rength	Strength
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient /A TILLETIA CARIES (UNII Inactive Ingredient SODIUM BICARBONAT	on Active Moie Ingrec C7000B9PQI	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name	ANEOUS		Basis of Str	rength	Strength 10000 [PNU] in 1 m]
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient/A TILLETIA CARIES (UNII Inactive Ingredient SODIUM BICARBONATI SODIUM CHLORIDE (UN	on Active Moie Ingrec C7000B9PQI S E (UNII: 8 MDF5 NII: 451W47IQ8	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name	ANEOUS		Basis of Str	rength	Strength 10000 [PNU] in 1 m]
wheat bunt injection, so Product Information Product Type Route of Administration Active Ingredient/A TILLETIA CARIES (UNIIN Inactive Ingredient SODIUM BICARBONATION SODIUM CHLORIDE (UNII) PHENOL (UNII: 339NCG4	on Active Moie Ingrec Ingrec C7000B9PQI S E (UNII: 8 MDF5 NII: 451W47IQ8 44TV)	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name	ANEOUS		Basis of Str	rength	Strength 10000 [PNU] in 1 m]
wheat bunt injection, so Product Information Product Type Route of Administration Active Ingredient/A TILLETIA CARIES (UNIIN Inactive Ingredient SODIUM BICARBONATION SODIUM CHLORIDE (UNII) PHENOL (UNII: 339NCG4	on Active Moie Ingrec Ingrec C7000B9PQI S E (UNII: 8 MDF5 NII: 451W47IQ8 44TV)	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name	ANEOUS		Basis of Str	rength	Strength 10000 [PNU] in 1 m]
wheat bunt injection, so Product Information Product Type Route of Administration Active Ingredient/A TILLETIA CARIES (UNII Inactive Ingredient SODIUM BICARBONATI SODIUM BICARBONATI SODIUM CHLORIDE (UN PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0KG	on Active Moie Ingrec Ingrec C7000B9PQI S E (UNII: 8 MDF5 NII: 451W47IQ8 44TV)	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name	ANEOUS		Basis of Str	rength	Strength 10000 [PNU] in 1 m]
Product Type Route of Administratio Active Ingredient/A	on Active Moie Ingred Ingred C7000B9PQI S E (UNII: 8 MDF5 NII: 451W47IQ8 44TV) OOR)	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name	ANEOUS	I) T	Basis of Str	rength RIES	Strength 10000 [PNU] in 1 m]
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient/A TILLETIA CARIES (UNII Inactive Ingredient SODIUM BICARBONAT SODIUM CHLORIDE (UN PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0KG Packaging	on on Active Moie Ingrec : C7000B9PQI :S E (UNII: 8 MDF5 NII: 451W47IQ8 44TV) 00 R) Pac	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name V39QO) X)	ANEOUS	I) T	Basis of Str Illetia Caf	rength RIES	Strength 10000 [PNU] in 1 ml Strength
wheat bunt injection, so Product Informatio Product Type Route of Administratio Active Ingredient/A TILLETIA CARIES (UNII Inactive Ingredient SODIUM BICARBONATT SODIUM CHLORIDE (UN PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0KO Packaging # Item Code	on on Son Son Son Son Son Son Son Son Son Son	INTRADERMAL, SUBCUT ty lient Name) (TILLETIA CARIES - UNI Ingredient Name SV39QO) X) X)	ANEOUS	I) T	Basis of Str Illetia Caf	rength RIES	Strength 10000 [PNU] in 1 ml Strength

4 NDC:36987-2172-4	50 mL in 1	VIAL, MULTI-DOSE				
Marketing Info	rmation					
Marketing Category		on Number or Monograph	Citation 1	Marketing Start D	ate M	arketing End Dat
BLA	BLA102192	0 1		8/29/1972		5
	1					
WHEAT STEM	RUST					
vheat stem rust inject	ion, solution					
Product Information	on					
Product T ype		HUMAN PRESCRIPTION DR	UG	Item Code (Sour	ce)	NDC:36987-2181
Route of Administration	on	SUBCUTANEOUS, INTRAD	DERMAL			
Active Ingredient//	Active Moi	e ty				
	Ing	edient Name		Basis of St	rength	Strength
PUCCINIA GRAMINIS (UUNII:00HJ02QBWN)	UNII: O0HJ02Q	BWN) (PUCCINIA GRAMINIS	5 -	PUCCINIA GRAMINIS		10000 [PNU] in 1 mL
Inactive Ingredien	te					
		Ingredient Name				Strength
SODIUM CHLORIDE (U	NII: 451W47IO	-				Strength
SODIUM BICARBONAT						
PHENOL (UNII: 339NCG	441 V J					
WATER (UNII: 059QF0K						
WATER (UNII: 059QF0K	.00R)	ckage Description	Marketii	ng Start Date	Mark	ceting End Date
WATER (UNII: 059QF0K Packaging # Item Code	OOR)	s kage Description IAL, MULTI-DOSE	Marketin	ıg Start Date	Mark	ceting End Date
WATER (UNII: 059QF0K Packaging # Item Code 1 NDC:36987-2181-1	200R) Pac 5 mL in 1 V	0	Marketin	ng Start Date	Mark	seting End Date
WATER (UNII: 059QF0K Packaging I NDC:36987-2181-1 NDC:36987-2181-2	EOOR) Frace 5 mL in 1 V 10 mL in 1	IAL, MULTI-DOSE	Marketin	ıg Start Date	Mark	seting End Date
 PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging Item Code NDC:36987-2181-1 NDC:36987-2181-2 NDC:36987-2181-3 NDC:36987-2181-3 	ECOOR) ECOOR E	IAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	ıg Start Date	Mark	ceting End Date
WATER (UNII: 059QF0K Packaging # Item Code 1 NDC:36987-2181-1 2 NDC:36987-2181-2 3 NDC:36987-2181-3	ECOOR) ECOOR E	IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	ng Start Date	Marł	eting End Date
WATER (UNII: 059QF0K Packaging # Item Code 1 NDC:36987-2181-1 2 NDC:36987-2181-2 3 NDC:36987-2181-3	ECOOR) ECOOR E	IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	ng Start Date	Mark	ceting End Date
 WATER (UNII: 059QF0K Packaging Item Code NDC:36987-2181-1 NDC:36987-2181-2 NDC:36987-2181-3 NDC:36987-2181-3 	COOR) 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 Frmation	IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE		ıg Start Date Marketing Start D		seting End Date arketing End Dat
WATER (UNII: 059QF0K I I I NDC:36987-2181-1 I NDC:36987-2181-2 I NDC:36987-2181-3 I NDC:36987-2181-3 I NDC:36987-2181-3 I NDC:36987-2181-3 I NDC:36987-2181-4	COOR) 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 Frmation	IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation 1			

CURVULARIA INEQUALIS

curvularia inequalis injection, solution

	on						
Product T ype		HUMAN PRESCRIPTION D	RUG	Ite m	Code (Source)	N	DC:36987-1956
Route of Administrati	on	SUBCUTANEOUS, INTRA	DERMAL				
Active Ingredient/	Active Moi	ety					
	Ingr	edient Name			Basis of Stre	ngth	Strength
CURVULARIA INAEQU UNII:W042YAB8JC)	ALIS (UNII: WO)42YAB8JC) (CURVULARIA	A INAEQUALIS	-	CURVULARIA INAEQUALIS		10000 [PNU] in 1 mL
Inactive Ingredien	te						
mactive ingreaten		Ingredient Name					Strength
SO DIUM BICARBO NAT	TE (UNII: 8 MDF	0					Strength
	•	• /					
SUDIUM CHLUKIDE (U	1111. 4JIW4/ IQU	UA)					
SODIUM CHLORIDE (U PHENOL (UNII: 339NCG	-						
PHENOL (UNII: 339NCG	644TV)						
PHENOL (UNII: 339NCG	644TV)						
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K	644TV)	57)					
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging	344TV) XOOR)	ckage Description	Marketi	ng Sta	nrt Date	Marke	ting End Date
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging # Item Code	44TV) COOR) Pac		Marketi	ng Sta	nrt Date N	Marke	ting End Date
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging # Item Code 1 NDC:36987-1956-1	644TV) (COOR) Pac 5 mL in 1 V	ckage Description	Marketi	ng Sta	nrt Date M	Marke	ting End Date
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging	44TV) COOR) Pac 5 mL in 1 V 10 mL in 1	c kage Description /IAL, MULTI-DOSE	Marketi	ng Sta	nrt Date	Marke	ting End Date
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging # Item Code 1 NDC:36987-1956-1 2 NDC:36987-1956-2	44TV) COOR) Pac 5 mL in 1 V 10 mL in 1	C kage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	nrt Date M	Marke	ting End 1
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging # Item Code 1 NDC:36987-1956-1 2 NDC:36987-1956-2 3 NDC:36987-1956-3	44TV) COOR) Pac 5 mL in 1 V 10 mL in 1 30 mL in 1	C kage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	nrt Date N	Marke	ting End Date
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K I Kaging I NDC:36987-1956-1 I NDC:36987-1956-2 NDC:36987-1956-3 I NDC:36987-1956-3 I NDC:36987-1956-4	A44TV) COOR) 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	C kage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	nrt Date N	Marke	ting End Date
PHENOL (UNII: 339NCG WATER (UNII: 059QF0K I Kaging I NDC:36987-1956-1 I NDC:36987-1956-2 NDC:36987-1956-3 NDC:36987-1956-4	A44TV) COOR) 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	C kage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marke ti	ng Sta	nrt Date	Marke	ting End Date
 PHENOL (UNII: 339NCG WATER (UNII: 059QF0K Packaging # Item Code NDC:36987-1956-1 NDC:36987-1956-2 NDC:36987-1956-3 	A44TV) COOR 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	C kage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			rt Date N		ting End Date •keting End Da

FUSARIUM COMPACTUM

fusarium compactum injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1974
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FUSARIUM COMPACTUM (UNII: V4OQR60A5P) (FUSARIUM COMPACTUM - UNII:V4OQR60A5P)	FUSARIUM COMPACTUM	10000 [PNU] in 1 mL

		Ingredient Name			Strength
s	ODIUM CHLORIDE (UI	NII: 451W47IQ8X)			
s	O DIUM BICARBO NAT	E (UNII: 8 MDF5V39QO)			
P	HENOL (UNII: 339NCG4	14TV)			
W	VATER (UNII: 059QF0K	20R)			
-					
P	Packaging				
#	Item Code	Package Description	Marke	ting Start Date	Marketing End Date
1	NDC:36987-1974-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-1974-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-1974-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-1974-4	50 mL in 1 VIAL, MULTI-DOSE			
		mation			
N	Marketing Info	mation			
	Marketing Infor Marketing Category	Application Number or Monograph	Citation	Marketing Start Dat	e Marketing End Date

PHOMA GLOMERATA

phoma glomerata injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2055
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/A	Active Moiety		
	Ingredient Name	Basis of	Strength Strength
PHOMA GLOMERATA (UNII:UPX000VMIF)	UNII: UPX000VMIF) (PHOMA GLOMERATA	A - PHOMA GLOMERA	10000 [PNU] ATA in 1 mL
Inactive Ingredient	S		
	Ingredient Name		Strength
SODIUM BICARBONATI	E (UNII: 8MDF5V39QO)		
SODIUM CHLORIDE (UN	NII: 451W47IQ8X)		
PHENOL (UNII: 339NCG4	44TV)		
WATER (UNII: 059QF0KC	20 R)		
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Dat
1 NDC:36987-2055-1	5 mL in 1 VIAL, MULTI-DOSE		

Marketing Info Marketing Category	rmation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing Info	rmation		
4 NDC:36987-2055-4	50 mL in 1 VIAL, MULTI-DOSE		
3 NDC:36987-2055-3	30 mL in 1 VIAL, MULTI-DOSE		
	10 mL in 1 VIAL, MULTI-DOSE		

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

Nelco Laboratories, Inc.