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.

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**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.<sup>(1)</sup>(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.<sup>(2)</sup> 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.<sup>(4)</sup>(*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.<sup>(3)</sup> 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.<sup>(5)</sup>

## 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 0.1 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  $\mu$ g/ml are associated with therapeutic effects. Toxicity is particularly apparent at concentrations greater than 20  $\mu$ 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  $\mu$ 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. <sup>(6)</sup>

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

#### Diagnostic Use: Intradermal Skin Testing Method

Do not perform intradermal test with allergens which have evoked a 2+ or greater response to a Scratch test. Clean test area with alcohol, place sites 5 cm apart using separate sterile tuberculin syringe and a 25 gauge needle for each allergen. Insert needle tip, bevel up, into intracutaneous space. Avoid injecting into blood vessel, pull back gently on syringe plunger, if blood enters syringe change position of needle. The recommended dosage and range for intradermal testing is 0.1 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 0.1 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. <sup>(6)</sup>

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	0.1
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	0.1
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	0.1
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	0.1
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.

4. 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.

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 ALLERGEANIC EXTRACT FOR INTRADERMAL TESTING Lot No. . EXP. DATE NELLCO LABSINCES Total unitial dose 0.02 ml See PARK. M.Y. 11729

## ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

#### **Product Information**

Product Type	HUMAN PRESCRIPTION DRUG
Route of Administration	INTRADERMAL, SUBCUTANEOUS

Active Ingredient/Active Moiety						
Ingredient Name	<b>Basis of Strength</b>	Strength				
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)	AS PERGILLUS FUMIGATUS	0.05 g in 1 mL				
Inactive Ingredients						

NDC:36987-1854

Item Code (Source)

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

P	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:36987-1854-1	5 mL in 1 VIAL, MULTI-DOSE						
2	NDC:36987-1854-2	10 mL in 1 VIAL, MULTI-DOSE						
3	NDC:36987-1854-3	30 mL in 1 VIAL, MULTI-DOSE						
4	NDC:36987-1854-4	50 mL in 1 VIAL, MULTI-DOSE						

Marketing Info	ormation						
Marketing Category	Applicatio	on Number or Monograp	oh Citation	Marketin	g Start Date	Marketi	ng End Dat
BLA	BLA102192			08/29/1972			
ALTERNARIA	ALTERN	АТА					
lternaria alternata in							
Product Informat	ion						
Product Type		HUMAN PRESCRIPTION I	ORUG	Item Co	de (Source)	NDC:3	6987-1863
Route of Administra	tion	INTRADERMAL, SUBCUT	ΓANEOUS				
Active Ingredient	/Active Moi	etv					
		gredient Name			Basis of St	trength	Strengtl
ALTERNARIA ALTER UNII:52B29REC7H)		329 REC7H) (ALTERNARIA	. ALTERNATA -		ALTERNARIA ALTERNATA		0.05 g in 1 mL
Inactive Ingredie	nts	Ingredient Name				St	rength
SODIUM CHLORIDE (	UNII: 451W47IQ	BX)					
SODIUM BICARBONA		5V39QO)					
WATER (UNII: 059QF0							
PHENOL (UNII: 339NC							
GLYCERIN (UNII: PDC)	GASCUUX)						
Packaging							
# Item Code	Pa	ckage Description	Market	ting Start	Date M	larketing	End Date
1 NDC:36987-1863-1		IAL, MULTI-DOSE					
2 NDC:36987-1863-2		VIAL, MULTI-DOSE					
<b>3</b> NDC:36987-1863-3		VIAL, MULTI-DOSE					
4 NDC:36987-1863-4	50 mL in 1	VIAL, MULTI-DOSE					
	.•						
Marketing Info	ormation						
Marketing Info Marketing Category		on Number or Monograp	oh Citation	Marketin	g Start Date	Marketi	ng End Dat

# ASPERGILLUS FLAVUS

aspergillus flavus injection, solution

	on						
Product T ype		HUMAN PRESCRIPTION DE	UG	Item Coo	le (Source)	NDC:	36987-1872
Route of Administrati	ion	SUBCUTANEOUS, INTRAE	DERMAL				
Active Ingredient/	Active Moi	ety					
	Ing	redient Name			Basis of St	rength	Strength
ASPERGILLUS FLAVU	<b>S</b> (UNII: 3J888	Y9L13) (ASPERGILLUS FLAV	/US - UNII:3J8	88Y9L13)	ASPERGILLUS	5 FLAVUS	0.05g in 1m
Inactive Ingredien	its						
Ū		Ingredient Name				St	trength
SO DIUM BICARBONAT	<b>FE</b> (UNII: 8 MDF	0					
	JNII: 451W47IQ	3X)					
SODIUM CHLORIDE (U		)					
WATER (UNII: 059QF0k		,					
WATER (UNII: 059QF0k	KO0R)	)					
	KO0R) G44TV)						
WATER (UNII: 059QF0K PHENOL (UNII: 339NCC	KO0R) G44TV)	,					
WATER (UNII: 059QF0K PHENOL (UNII: 339NCC	KO0R) G44TV)						
WATER (UNII: 059QF0K PHENOL (UNII: 339NCG GLYCERIN (UNII: PDC6	KO0R) G44TV)						
WATER (UNII: 059QF0K PHENOL (UNII: 339NCG GLYCERIN (UNII: PDC6 Packaging	KOOR) G44TV) A3C0OX)	:kage Description	Marketi	ng Start I	Date N	farketing	g End Date
WATER (UNII: 059QF0K PHENOL (UNII: 339NCG GLYCERIN (UNII: PDC6 Packaging	(OOR) G44TV) A3C0OX) Pac		Marketi	ng Start I	Date M	farketing	g End Date
WATER (UNII: 059QF0K PHENOL (UNII: 339NCG GLYCERIN (UNII: PDC6 Packaging # Item Code	<pre>KOOR) G44TV) A3C0OX)  Figure A Content Co</pre>	ekage Description	Marketi	ng Start I	Date M	ſarketing	g End Date
WATER (UNII: 059QF0K         PHENOL (UNII: 339NCG         GLYCERIN (UNII: PDC6         Packaging         #       Item Code         1       NDC:36987-1872-1	<pre>KOOR) G44TV) A3COOX) A3COOX 5 mL in 1 V 10 mL in 1</pre>	t <b>kage Description</b> IAL, MULTI-DOSE	Marketi	ng Start I	Date M	ſarketing	g End Date
WATER (UNII: 059QF0K         PHENOL (UNII: 339NCG         GUERIN (UNII: PDC6         Packaging         I         NDC:36987-1872-1         NDC:36987-1872-2	KOO R) G44TV) A3COOX) A3COOX) D10 N 1 1 V 10 mL in 1 30 mL in 1	E <b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start I	Date M	ſarketing	g End Date
WATER (UNII: 059QF0F         PHENOL (UNII: 339NCG         VCERIN (UNII: PDC6         I         Item Code         I         NDC:36987-1872-1         NDC:36987-1872-2         NDC:36987-1872-3	KOO R) G44TV) A3COOX) A3COOX) D10 N 1 1 V 10 mL in 1 30 mL in 1	E <b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start I	Date M	larketing	g End Date
WATER (UNII: 059QF0F         PHENOL (UNII: 339NCG         VCERIN (UNII: PDC6         Particular         Image: Comparison of the tem tem tem tem tem tem tem tem tem te	KOO R) G44TV) A3COOX) A3COOX) D10 N 1 1 V 10 mL in 1 30 mL in 1	E <b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start I	Date M	ſarketing	g End Date
<ul> <li>WATER (UNII: 059QF0F</li> <li>PHENOL (UNII: 339NCG</li> <li>VCERIN (UNII: PDC6</li> <li>PCC36987-1872-1</li> <li>NDC:36987-1872-2</li> <li>NDC:36987-1872-3</li> <li>NDC:36987-1872-4</li> </ul>	KOO R) G44TV) A3CO X) A3CO	E <b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start I	Date M	ſarketing	g End Date
WATER (UNII: 059QF0F         PHENOL (UNII: 339NCG         GLYCERIN (UNII: PDC6         #         Item Code         1         NDC:36987-1872-1         2         NDC:36987-1872-3         NDC:36987-1872-4	KOO R) G44TV) <pg44tv)< p=""> G44TV) G44TV) <pg< td=""><td>E<b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE</td><td></td><td></td><td></td><td></td><td></td></pg<></pg44tv)<>	E <b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE					
WATER (UNII: 059QF0F         PHENOL (UNII: 339NCG         UNII: 9DC6         IVCERIN (UNII: PDC6         I         NDC:36987-1872-1         NDC:36987-1872-2         NDC:36987-1872-3         NDC:36987-1872-4	KOO R) G44TV) <pg44tv)< p=""> G44TV) G44TV) <pg< td=""><td>E<b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE</td><td>Citation</td><td></td><td>Date M g Start Date</td><td></td><td>g End Date ing End Date</td></pg<></pg44tv)<>	E <b>kage Description</b> IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation		Date M g Start Date		g End Date ing End Date

## ASPERGILLUS REPENS

aspergillus repens injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1881
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
<b>EURO TIUM HERBARIO RUM</b> (UNII: 49 W168AES4) (EURO TIUM HERBARIO RUM - UNII: 49 W168AES4)	EUROTIUM HERBARIORUM	0.05 g in 1 mL			

		Ingredient Name			Stren	gth
SODIUM						
SODIUM	1 BICARBONAT	E (UNII: 8 MDF5V39QO)				
WATER	(UNII: 059QF0K	O0R)				
PHENOI	L (UNII: 339 NCG	44TV)				
GLYCE	RIN (UNII: PDC6	A3C0OX)				
Packag	ging					
# ]	Item Code	Package Description	Marke	ting Start Date	Marketing En	d Date
1 NDC:3	86987-1881-1	5 mL in 1 VIAL, MULTI-DOSE				
2 NDC:3	86987-1881-2	10 mL in 1 VIAL, MULTI-DOSE				
3 NDC:3	86987-1881-3	30 mL in 1 VIAL, MULTI-DOSE				
4 NDC:3	86987-1881-4	50 mL in 1 VIAL, MULTI-DOSE				
Mark	eting Info	rmation				
Market	ting Category	Application Number or Monograph	Citation	Marketing Start D	ate Marketing	End Da
BLA		BLA102192		08/29/1972		

ASPERGILLUS NIGER					
aspergillus niger injection, solution					
usperginus inger injection, solution					
Product Information					
Product T ype	HUMAN PRESCRIPTION DRUG	Ite m Co	de (Source)	NDC:36	987-1890
Route of Administration	SUBCUTANEOUS, INTRADERMAL				
Active Ingredient/Active Moie	ety				
Ing	redient Name		Basis of Str	rength	Strength
ASPERGILLUS NIGER VAR. NIGER (UNIGER - UNII:910A40ANG6)	JNII: 910A40ANG6) (ASPERGILLUS NIGER	VAR.	ASPERGILLUS N VAR. NIGER	NGER	0.05 g in 1 mL
Inactive Ingredients					
	Ingredient Name			Stre	ngth
SODIUM CHLORIDE (UNII: 451W47IQ8	3X)				
SODIUM BICARBONATE (UNII: 8 MDF	5V39QO)				
PHENOL (UNII: 339NCG44TV)					
WATER (UNII: 059QF0KO0R)					
GLYCERIN (UNII: PDC6A3C0OX)					
Packaging					

# Item Code	Pa	ckage Description	Marketin	ng Start Date	Mai	rketing	End Date
1 NDC:36987-1890-1	5 mL in 1 V	/IAL, MULTI-DOSE					
<b>2</b> NDC:36987-1890-2	10 mL in 1	VIAL, MULTI-DOSE					
<b>3</b> NDC:36987-1890-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC:36987-1890-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Info	rmation						
Marketing Category		on Number or Monograph C	Citation I	Marketing Start 1	Date I	Marketi	ng End Date
BLA	BLA102192	Ŭ .		8/29/1972			0
aspergillus terreus inj Product Informati	ection, solutio	on	C	Incer Code (Sou		NDC-2	6097 1900
aspergillus terreus inj Product Informati Product Type	ection, solutio	ON HUMAN PRESCRIPTION DRU		Item Code (Sou	irce)	NDC:3	6987-1899
aspergillus terreus inj Product Informati	ection, solutio	on		Item Code (Sou	irce)	NDC:3	6987-1899
aspergillus terreus inj Product Informati Product Type	ection, solutio	ON HUMAN PRESCRIPTION DRU		Item Code (Sou	rce)	NDC:3	6987-1899
aspergillus terreus inj <b>Product Informati</b> Product Type Route of Administrat	ection, solutio	ON HUMAN PRESCRIPTION DRU INTRADERMAL, SUBCUTAN		Item Code (Sou	rce)	NDC:3	6987-1899
aspergillus terreus inj <b>Product Informati</b> Product Type Route of Administrat	ection, solutio on ion <b>'Active Moi</b>	ON HUMAN PRESCRIPTION DRU INTRADERMAL, SUBCUTAN			rce) s of Stre		
Aspergillus terreus inj Product Informati Product Type Route of Administrat Active Ingredient	ection, solutio on ion Active Moie In	HUMAN PRESCRIPTION DRU INTRADERMAL, SUBCUTAN	EOUS	Basi	s of Stre		6987-1899 Strength 0.05 g in 1 mL
Product Type	ection, solutio on ion 'Active Moi	HUMAN PRESCRIPTION DRU INTRADERMAL, SUBCUTAN					

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

Packaging							
Item Code	Package Description	Marketing Start Date	Marketing End Date				
NDC:36987-1899-1	5 mL in 1 VIAL, MULTI-DOSE						
NDC:36987-1899-2	10 mL in 1 VIAL, MULTI-DOSE						
NDC:36987-1899-3	30 mL in 1 VIAL, MULTI-DOSE						
NDC:36987-1899-4	50 mL in 1 VIAL, MULTI-DOSE						
•	0 0	Item CodePackage DescriptionNDC:36987-1899-15 mL in 1 VIAL, MULTI-DOSENDC:36987-1899-210 mL in 1 VIAL, MULTI-DOSENDC:36987-1899-330 mL in 1 VIAL, MULTI-DOSE	Item CodePackage DescriptionMarketing Start DateNDC:36987-1899-15 mL in 1 VIAL, MULTI-DOSENDC:36987-1899-210 mL in 1 VIAL, MULTI-DOSENDC:36987-1899-330 mL in 1 VIAL, MULTI-DOSE				

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

botrvtis cir		IEREA						
	nerea injecti	on, solution						
Product	Informatio	on						
Product T	'yp e		HUMAN PRESCRIPTION DE	UG	Item Cod	le (Source)	NDC	:36987-1908
Route of A	dministratio	on	SUBCUTANEOUS, INTRAE	DERMAL				
Active In	ngredient/A	Active Moi	ety					
		Ing	gredient Name			Basis of St	rength	Strength
BOTRYTIS	6 CINEREA (U	JNII: TBW5331	3S7) (BOTRYTIS CINEREA -	UNII:TBW5331	3S7)	BOTRYTIS C	INEREA	$0.05\;g$ in $1mL$
Inactive	Ingredien	ts	Ingredient Name				G	Strength
SO DIUM B	ICARBONAT	' <b>E</b> (UNII: 8 MDF	•					firengen
		NII: 451W47IQ	- ,					
	UNII: 339 NCG		,					
WATER (UI	NII: 059QF0K	.00R)						
GLYCERIN	I (UNII: PDC6	A3C0OX)						
Packagir	ıg							
•	ng em Code	Pa	ckage Description	Marketi	ng Start I	Date N	<i>f</i> arke tin	g End Date
# Ite	em Code		c <b>kage Description</b> /IAL, MULTI-DOSE	Marketi	ng Start I	Date M	<i>l</i> arketin	g End Date
# Ite 1 NDC:369	em Code 87-1908-1	5 mL in 1 V		Marketin	ng Start I	Date M	<i>l</i> arketin	g End Date
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> </ul>	em Code 87-1908-1 87-1908-2 87-1908-3	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start I	Date M	<b>Aarketin</b>	g End Date
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> </ul>	em Code 87-1908-1 87-1908-2 87-1908-3	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketin	ng Start I	Date M	⁄larke tin	g End Date
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> </ul>	em Code 87-1908-1 87-1908-2 87-1908-3	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start I	Date M	<b>A</b> arketin	g End Date
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> <li>4 NDC:369</li> </ul>	em Code 87-1908-1 87-1908-2 87-1908-3	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	Marketin	ng Start I	Date M	<b>farketin</b>	g End Date
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> <li>4 NDC:369</li> </ul>	em Code 87-1908-1 87-1908-2 87-1908-3 87-1908-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			Date N		g End Date ting End Date
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> <li>4 NDC:369</li> <li>4 NDC:369</li> </ul>	em Code 87-1908-1 187-1908-2 187-1908-3 187-1908-4 187-1908-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation				
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> <li>4 NDC:369</li> <li>4 NDC:369</li> </ul>	em Code 87-1908-1 187-1908-2 187-1908-3 187-1908-4 187-1908-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 <b>rmation</b> Applicatio	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marketing			
<ul> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> <li>4 NDC:369</li> </ul>	em Code 87-1908-1 187-1908-2 187-1908-3 187-1908-4 187-1908-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 <b>rmation</b> Applicatio	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marketing			
<ul> <li># Ite</li> <li>1 NDC:369</li> <li>2 NDC:369</li> <li>3 NDC:369</li> <li>4 NDC:369</li> <li>4 NDC:369</li> </ul>	em Code 87-1908-1 187-1908-2 187-1908-3 187-1908-4 187-1908-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 rmation Applicatio	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marketing			

Product Information						
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1917			
Route of Administration	SUBCUTANEOUS, INTRADERMAL					
Route of Administration	SUBCUTANEOUS, INTRADERMAL					

Active Ingredient/	Active Moie	ty						
	Ing	redient Name			Basis of	f Streng	gth	Strength
CANDIDA ALBICANS (U	JNII: 4D7G21HD	BC) (CANDIDA ALBICANS	5 - UNII:4D7G2	21HDBC)	CANDIDA	ALBICA	NS	0.05 g in 1 m
Inactive Ingredien	te							
macuve ingretien		Ingredient Name					S	trength
SODIUM CHLORIDE (U	NII: 451W47IO8	0					0	trength
SODIUM BICARBONAT								
PHENOL (UNII: 339NCG								
WATER (UNII: 059QF0K								
GLYCERIN (UNII: PDC6.								
Packaging								
# Item Code		kage Description	Market	ting Start I	Date	Mark	eting	g End Date
<b>1</b> NDC:36987-1917-1		AL, MULTI-DOSE						
2 NDC:36987-1917-2		IAL, MULTI-DOSE						
<b>3</b> NDC:36987-1917-3		IAL, MULTI-DOSE						
4 NDC:36987-1917-4	50 mL in 1 v	IAL, MULTI-DOSE						
Marketing Info								
Marketing Category	Application	n Number or Monograp	h Citation	Marketin	g Start Da	te Ma	irke	ting End Dat
BLA	BLA102192			08/29/1972				
ACREMONIUM		UM						
cremonium strictum								
Product Information	on							
Product Type		HUMAN PRESCRIPTION D	RUG	Item Co	de (Sourc	e)	NDC	36987-1926
Route of Administrati	on	INTRADERMAL, SUBCUT	ANEOUS					
Active Ingredient/	Active Moie	ty						
	Ing	redient Name			Basis o	f Stren	gth	Strengtl
ACREMONIUM STRICT UNII:3F36 V0451W)	' <b>UM</b> (UNII: 3F36	V0451W) (ACREMONIUM	STRICTUM -		ACREMON STRICTUM			0.05 g in 1 mL
Inactive Ingredien	ts							
		Ingredient Name					S	trength

 Ingredient Name
 Strength

 SODIUM CHLORIDE (UNII: 451W47IQ8X)

 SODIUM BICARBONATE (UNII: 8MDF5V39QO)

 PHENOL (UNII: 339NCG44TV)

# WATER (UNII: 059QF0KO0R)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging							
#	Item Code	Package Description	Marke	ting Start Date M	larketing End Date		
1 1	NDC:36987-1926-1	5 mL in 1 VIAL, MULTI-DOSE					
2	NDC:36987-1926-2	10 mL in 1 VIAL, MULTI-DOSE					
3 1	NDC:36987-1926-3	30 mL in 1 VIAL, MULTI-DOSE					
<b>4</b> ľ	NDC:36987-1926-4	50 mL in 1 VIAL, MULTI-DOSE					
Marketing Information							
M	arketing Category	Application Number or Monograph	Citation	Marketing Start Date	Marketing End Date		
BL.	A	BLA102192		08/29/1972			

### **TRICHOTHECIUM ROSEUM**

trichothecium roseum injection, solution

#### **Product Information**

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1935
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
<b>TRICHO THECIUM ROSEUM</b> (UNII: TGO054E310) (TRICHO THECIUM ROSEUM - UNII: TGO054E310)	TRICHOTHECIUM ROSEUM	0.05 g in 1 mL

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

#### Packaging

	0 0			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-1935-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-1935-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-1935-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-1935-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
BLA	BLA102192	08/29/1972				
CI ADOSDODII	IM CLADOSDODIOIDES					
CLADOSPORIU	JM CLADOSPORIOIDES					

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1944
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of S	strength	Strength
<b>CLADO SPO RIUM CLADO SPO RIO IDES</b> (UNII: 4ZWY20GTGO) (CLADO SPO RIUM CLADO SPO RIO IDES - UNII:4ZWY20GTGO)	CLADOSPORI CLADOSPORI		0.05 g in 1 mL
Inactive Ingredients			
Ingredient Name		Strei	ıgth
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM BICARBONATE (UNII: 8 MDF5V39QO)			
PHENOL (UNII: 339NCG44TV)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			

Р	Packaging							
#	Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>				
1	NDC:36987-1944-1	5 mL in 1 VIAL, MULTI-DOSE						
2	NDC:36987-1944-2	10 mL in 1 VIAL, MULTI-DOSE						
3	NDC:36987-1944-3	30 mL in 1 VIAL, MULTI-DOSE						
4	NDC:36987-1944-4	50 mL in 1 VIAL, MULTI-DOSE						

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

# **CHAETOMIUM GLOBOSUM**

chaetomium globosum injection, solution

	luct Informatio	on						
Produ	uct T yp e		HUMAN PRESCRIPTION D	RUG	Item Cod	le (Source)	NDC:3	6987-1953
Route	of Administration	on	SUBCUTANEOUS, INTRA	DERMAL				
Activ	ve Ingredient/A	Active Moi	ety					
		Ing	gredient Name			Basis of S	trength	Strength
	<b>TOMIUM GLOBO</b> 016WB8B8A)	<b>SUM</b> (UNII: 50	16WB8B8A) (CHAETOMU	JM GLOBOSU	JM -	CHAETOMIU GLOBOSUM		0.05 g in 1 mL
Inact	ive Ingredient	ts						
			Ingredient Name				Sti	ength
SODI	UM CHLORIDE (U	NII: 451W47IQ8						0
SODI	UM BICARBONAT	'E (UNII: 8 MDF	5V39QO)					
PHENO	<b>DL</b> (UNII: 339NCG	44TV)						
WATE	E <b>R</b> (UNII: 059QF0K	O0R)						
GLYC	ERIN (UNII: PDC6	A3C0OX)						
Pack	aging							
#	Item Code	Pac	kage Description	Marke	ting Start I	Date M	farketing	End Date
1 NDC	2:36987-1953-1	5 mL in 1 V	IAL, MULTI-DOSE					
2 NDC	2:36987-1953-2	10 mL in 1	VIAL, MULTI-DOSE					
3 NDC	2:36987-1953-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC	2:36987-1953-4	50 mL in 1	VIAL, MULTI-DOSE					
	keting Info	rmation						
Mar			on Number or Monograp	h Citation	Marketing	g Start Date	Marketi	ng End Date
	ceting Category	Applicatio	in Humber of Monogrup			,		is Life Date
	ceting Category	Application BLA102192	in tumber of hionograp		08/29/1972	,		ig Liid Dat

EPICOCCUM NIGRUM					
epicoccum nigrum injection, solut	ion				
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Co	de (Source)	NDC	:36987-1971
Route of Administration	SUBCUTANEOUS, INTRADERMAL				
Active Ingredient/Active Mo	iety				
In	gredient Name		Basis of Stren	gth	Strength
EPICOCCUM NIGRUM (UNII: 87U156	LEN7) (EPICOCCUM NIGRUM - UNII:87U156	LEN7)	EPICOCCUM NIG	RUM	0.05g in $1mL$

Inactive Ingredie	nts			
	Ingredient Name			Strength
SODIUM CHLORIDE (	JNII: 451W47IQ8X)			
SODIUM BICARBONA	FE (UNII: 8 MDF5V39QO)			
PHENOL (UNII: 339NC)	G44TV)			
WATER (UNII: 059QF0)	KOOR)			
GLYCERIN (UNII: PDC6	A3C0OX)			
Packaging				
# Item Code	Package Description	Market	ting Start Date	Marketing End Date
1 NDC:36987-1971-1	5 mL in 1 VIAL, MULTI-DOSE			
2 NDC:36987-1971-3	30 mL in 1 VIAL, MULTI-DOSE			
<b>3</b> NDC:36987-1971-4	50 mL in 1 VIAL, MULTI-DOSE			
4 NDC:36987-1971-2	10 mL in 1 VIAL, MULTI-DOSE			
Marketing Info	rmation			
0				
Marketing Category	Application Number or Monograph	Citation	Marketing Start Date	Marketing End Date

<b>GEOTRICHUM CANDI</b>	DUM				
geotrichum candidum injection, s	olution				
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Coo	le (Source)	NDC:3	6987-1989
Route of Administration	SUBCUTANEOUS, INTRADERMAL				
Active Ingredient/Active Mo	iety				
II	igredient Name		Basis of Stre	ngth	Strength
GEOTRICHUM CANDIDUM (UNII: 59 UNII:5964J742O8)	64J742O8) (GEOTRICHUM CANDIDUM -		GEOTRICHUM CANDIDUM		0.05 g in 1 mL
Inactive Ingredients					
	Ingredient Name			St	rength
SODIUM CHLORIDE (UNII: 451W471	Q8X)				
SODIUM BICARBONATE (UNII: 8 MI	DF5V39QO)				
PHENOL (UNII: 339NCG44TV)					
WATER (UNII: 059QF0KO0R)					
GLYCERIN (UNII: PDC6A3C0OX)					

# Item Code	Package Description Ma	rketing Start Date N	Marketing End Date						
1 NDC:36987-1989-1	5 mL in 1 VIAL, MULTI-DOSE								
<b>2</b> NDC:36987-1989-2	10 mL in 1 VIAL, MULTI-DOSE								
<b>3</b> NDC:36987-1989-3	30 mL in 1 VIAL, MULTI-DOSE								
4 NDC:36987-1989-4	50 mL in 1 VIAL, MULTI-DOSE								
Marketing Information									
Marketing Category	Application Number or Monograph Citatio	n Marketing Start Date	Marketing End Date						
Marketing Category BLA		Marketing Start Date           08/29/1972	Marketing End Date						
	Application Number or Monograph Citatio	-	Marketing End Date						

<b>BIPOLARIS SO</b>	ROKINI	ANA					
bipolaris sorokiniana ii	njection, sol	ution					
Product Information							
Product Type	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	HUMAN PRESCRIPTION DE	RUG	Ite m Coo	le (Source)	NDC:3	6987-1998
Route of Administration	on	SUBCUTANEOUS, INTRAI	DERMAL		· · ·		
Active Ingredient//	Active Moi	ety					
	In	gredient Name			Basis of S	trength	Strength
<b>COCHLIOBOLUS SATI</b> UNII:3LN5B70U4W)	VUS (UNII: 3L	N5B70U4W) (COCHLIOBOL	US SATIVUS -		COCHLIOBO SATIVUS	LUS	0.05 g in 1 mL
Inactive Ingredien	ts						
		Ingredient Name				Sti	rength
SODIUM CHLORIDE (U	NII: 451W47IQ	8 X)					
SODIUM BICARBONAT	E (UNII: 8 MDF	5V39QO)					
PHENOL (UNII: 339NCG	44TV)						
WATER (UNII: 059QF0K	.00R)						
GLYCERIN (UNII: PDC6	A3C0OX)						
Packaging							
# Item Code	Pa	ckage Description	Marketii	ng Start I	Date N	<b>farketing</b>	End Date
1 NDC:36987-1998-1	5 mL in 1 V	/IAL, MULTI-DOSE					
<b>2</b> NDC:36987-1998-2	10 mL in 1	VIAL, MULTI-DOSE					
<b>3</b> NDC:36987-1998-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC:36987-1998-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Info	rmation						
Marketing Category	Applicatio	on Number or Monograph	n Citation	Marketing	g Start Date	Marketi	ng End Date
BLA	BLA102192			8/29/1972			

nacor planocus inj	ection, solution						
<b>Product Informa</b>	ition						
Product T ype		HUMAN PRESCRIPTION DR	UG	Ite m Cod	e (Source)	NDO	2:36987-2007
Route of Administra	ation	SUBCUTANEOUS, INTRAD	ERMAL				
Active Ingredien	nt/Active Moi	ety					
	Inş	redient Name			Basis of S	trength	Strength
MUCOR PLUMBEUS	(UNII: D740 1PWY	6E) (MUCOR PLUMBEUS - U	NII:D7401PW	Y6E)	MUCOR PLU	JMBEUS	0.05 g in 1 mL
SO DIUM CHLO RIDE	(UNII: 451W47IO)	Ingredient Name					Strength
Inactive Ingredie	- 1105	Ingredient Name					Strength
SODIUM CHLORIDE	(UNII: 451W47IQ8	3X)					
		5V39QO)					
PHENOL (UNII: 339 NO	CG44TV)	5V39QO)					
SODIUM BICARBON PHENOL (UNII: 339NO WATER (UNII: 059QF GLYCERIN (UNII: PDO	CG44TV) 50KO0R)	5V39QO)					
PHENOL (UNII: 339N) WATER (UNII: 059QF	CG44TV) 50KO0R)	5V39QO)					
PHENOL (UNII: 339N) WATER (UNII: 059QF	CG44TV) 50KO0R)	5V39QO)					
PHENOL (UNII: 339NG WATER (UNII: 059QF GLYCERIN (UNII: PDC	CG44TV) 50KO0R)	5V39QO)					
PHENOL (UNII: 339NG WATER (UNII: 059QF GLYCERIN (UNII: PDO Packaging	CG44TV) 70KO0R) C6A3C0OX)	5V39QO) Skage Description	Marketi	ng Start D	Date	Marketin	ng End Date
PHENOL (UNII: 339NG WATER (UNII: 059QF GLYCERIN (UNII: PDO Packaging	CG44TV) FOKOOR) C6A3COOX) Pac		Marketi	ng Start D	Date	Marketin	ng End Date
PHENOL (UNII: 339NG WATER (UNII: 059QF GLYCERIN (UNII: PDC Packaging # Item Code	CG44TV) 70K00R) C6A3C0OX) Pace 5 mL in 1 V	ckage Description	Marketi	ng Start D	Date	Marketin	ng End Date
PHENOL (UNII: 339N0         WATER (UNII: 059QF         GLYCERIN (UNII: PDO         Packaging         #       Item Code         1       NDC:36987-2007-1	CG44TV) 70K00R) C6A3C0OX) Pace 5 mL in 1 V 2 10 mL in 1	r <b>kage Description</b> TAL, MULTI-DOSE	Marketi	ng Start D	Date 2	Marketin	ng End Date
PHENOL (UNII: 339 NG         WATER (UNII: 059 QF         GUESTION (UNII: PDO)         PERIOD         UNIC:36987-2007-1         QUESTION         PUESTION	CG44TV) 70K00R) C6A3C0OX) C6A3C0OX) 20K00R C6A3C0OX) 20K00R 20K1 5 mL in 1 V 20K10 mL in 1 30 mL in 1	E <b>kage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start D	Date	Marketin	ng End Date
PHENOL (UNII: 339 NG)         WATER (UNII: 059QF)         GLYCERIN (UNII: PDO)         Packaging         #       Item Code         1       NDC:36987-2007-2         2       NDC:36987-2007-2         3       NDC:36987-2007-3	CG44TV) 70K00R) C6A3C0OX) C6A3C0OX) 20K00R C6A3C0OX) 20K00R 20K1 5 mL in 1 V 20K10 mL in 1 30 mL in 1	C <b>kage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start D	Date	Marketin	ng End Date
PHENOL (UNII: 339 NG)         WATER (UNII: 059QF)         GLYCERIN (UNII: PDO)         Packaging         #       Item Code         1       NDC:36987-2007-2         2       NDC:36987-2007-2         3       NDC:36987-2007-3	CG44TV) 70K00R) C6A3C0OX) C6A3C0OX) 20K00R C6A3C0OX) 20K00R 20K1 5 mL in 1 V 20K10 mL in 1 30 mL in 1	C <b>kage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start D	Date	Marketin	ng End Date
PHENOL (UNII: 339 NG)         WATER (UNII: 059QF)         GLYCERIN (UNII: PDO)         Packaging         #       Item Code         1       NDC:36987-2007-2         2       NDC:36987-2007-2         3       NDC:36987-2007-3	CG44TV) 70K00R) C6A3C0OX) C6A3C0OX) 20K01 C6A3C0OX) 20K11 5 mL in 1 V 20K10 mL in 1 30 mL in 1 4 50 mL in 1	C <b>kage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start D	Date	Marketin	ng End Date
PHENOL (UNII: 339N0         WATER (UNII: 059QF         GLYCERIN (UNII: PDO         Packaging         #         Item Code         1         NDC:36987-2007-2         3         NDC:36987-2007-3         4         NDC:36987-2007-4	CG44TV) 0KO0R) C6A3C0OX) C6A3C0OX) 5 mL in 1 V 2 10 mL in 1 3 0 mL in 1 4 50 mL in 1 4 50 mL in 1	C <b>kage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			Date		ng End Date eting End Date
PHENOL (UNII: 339N0         WATER (UNII: 059QF         GLYCERIN (UNII: PDO         PHENOL (UNII: PDO         I         NDC:36987-2007-1         NDC:36987-2007-3         NDC:36987-2007-3         NDC:36987-2007-4	CG44TV) 0KO0R) C6A3C0OX) C6A3C0OX) 5 mL in 1 V 2 10 mL in 1 3 0 mL in 1 4 50 mL in 1 4 50 mL in 1	<b>Skage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation				
PHENOL (UNII: 339N0         WATER (UNII: 059QF         GLYCERIN (UNII: PDO         Packaging         #       Item Code         1       NDC:36987-2007-1         2       NDC:36987-2007-2         3       NDC:36987-2007-3         4       NDC:36987-2007-4	CG44TV) 20 KO0 R) C6 A3 C0 OX) C6 A3 C0 OX) Pace Pace 5 mL in 1 V 10 mL in 1 3 0 mL in 1 3 0 mL in 1 5 0 mL in 1 5 0 mL in 1 4 50 mL in 1	<b>Skage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marketing			
PHENOL (UNII: 339N0         WATER (UNII: 059QF         GLYCERIN (UNII: PDO         Packaging         #       Item Code         1       NDC:36987-2007-1         2       NDC:36987-2007-2         3       NDC:36987-2007-3         4       NDC:36987-2007-4	CG44TV) 20 KO0 R) C6 A3 C0 OX) C6 A3 C0 OX) Pace Pace 5 mL in 1 V 10 mL in 1 3 0 mL in 1 3 0 mL in 1 5 0 mL in 1 5 0 mL in 1 4 50 mL in 1	<b>Skage Description</b> TAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marketing			

Product Information			
Product T ype	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2016
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

		ety						
	Ing	gredient Name			Basis	of Stre	ength	Strengt
NEUROSPORA INTERN JNII:2072U60DUI)	<b>IEDIA</b> (UNII: 2	072U60DUI) (NEUROSPORA	INTERMEDIA	-	NEUROS INTERME			0.05 g in 1 mL
JNII.2072000D01)					INTERM	LDIA		III I IIIL
Inactive Ingredien	ts							
		Ingredient Name					Str	ength
SODIUM BICARBONAT	T <b>E</b> (UNII: 8 MDF	5V39QO)						
SODIUM CHLORIDE (U	NII: 451W47IQ	8 X)						
PHENOL (UNII: 339NCG	44TV)							
WATER (UNII: 059QF0K	(O0R)							
GLYCERIN (UNII: PDC6)	A3C0OX)							
Packaging								
# Item Code		ckage Description	Marketi	ng Star	t Date	Ma	rketing 1	End Date
1 NDC:36987-2016-1	5 mL in 1 V	/IAL, MULTI-DOSE						
2 NDC:36987-2016-2	10 mL in 1	VIAL, MULTI-DOSE						
<b>3</b> NDC:36987-2016-3	30 mL in 1	VIAL, MULTI-DOSE						
4 NDC:36987-2016-4	50 mL in 1	VIAL, MULTI-DOSE						
Marketing Info	rmation							
Marketing Info Marketing Category		on Number or Monograph	Citation	Market	ing Start D	ate I	Marketin	ng End Date
Marketing Category		on Number or Monograph		<b>Market</b> 8/29/192	-	ate I	Marketin	ig End Date
Marketing Category	Applicatio	on Number or Monograph			-	ate I	Marketin	ig End Dat
Marketing Category BLA PENICILIUM C enicilium chrysogenu	Application BLA102192 CHRYSOC Im injection,	GENUM			-	Pate I	Marketin	ng End Dat
Marketing Category BLA PENICILIUM C penicilium chrysogenu Product Informatio	Application BLA102192 CHRYSOC Im injection,	<b>GENUM</b> solution	0	8/29/197	72			
Marketing Category BLA PENICILIUM Control of the second se	Application BLA102192 CHRYSOC Im injection,	<b>GENUM</b> solution HUMAN PRESCRIPTION DR	RUG	8/29/197	-			<b>1g End Dat</b>
Marketing Info Marketing Category BLA PENICILIUM C Denicilium chrysogenu Product Informatio Product Type Route of Administrati	Application BLA102192 CHRYSOC Im injection,	<b>GENUM</b> solution	RUG	8/29/197	72			
Marketing Category BLA PENICILIUM C penicilium chrysogenu Product Informatic Product Type	Application BLA102192 CHRYSOC Im injection, On	GENUM solution HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD	RUG	8/29/197	72			
Marketing Category BLA PENICILIUM Control of the second se	Application BLA102192 CHRYSOC Im injection, on on Active Moi	GENUM solution HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD	RUG	8/29/197	72 Code (Sour		NDC:36	
Marketing Category BLA PENICILIUM Content Product Information Product Type Route of Administration Active Ingredient/A	Application BLA102192 CHRYSOC Im injection, on Active Moin Ingr OGENUM VAR	GENUM solution HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD	0 RUG DERMAL 1PE1GCIG)	8/29/197	72 Code (Sour	rce) of Stre	NDC:36	5987-2043 Streng
Marketing Category BLA PENICILIUM C enicilium chrysogenu Product Informatio Product Type Route of Administrati Active Ingredient/A PENICILLIUM CHRYSOC	Application BLA102192 CHRYSOC Im injection, on on Active Moi Ingr GENUM VAR GENUM VAR. C	GENUM solution HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD ety redient Name . CHRYSO GENUM (UNII: 3Y	RUG DERMAL 1PE1GCIG)	8/29/197	72 Code (Sour Basis of PENICILLIUI	rce) of Stre	NDC:36	5987-2043 Streng M 0.05 g
Marketing Category BLA PENICILIUM C enicilium chrysogenu Product Informatio Product Type Route of Administrati Active Ingredient/A	Application BLA102192 CHRYSOC Im injection, on on Active Moi Ingr GENUM VAR GENUM VAR. C	GENUM solution HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD ety redient Name . CHRYSO GENUM (UNII: 3Y	RUG DERMAL 1PE1GCIG)	8/29/197	72 Code (Sour Basis of PENICILLIUI	rce) of Stre	NDC:36 <b>ngth</b> SOGENUI JM	5987-2043 Streng M 0.05 g

**SODIUM CHLORIDE** (UNII: 451W47IQ8X)

PHENOL (UNII: 339NCG44TV)

WATER (UNII: 059QF0K	CO0R)			
GLYCERIN (UNII: PDC6	A3C0OX)			
Packaging				
# Item Code	Package Description	Marke	ting Start Date	Marketing End Date
1 NDC:36987-2043-1	5 mL in 1 VIAL, MULTI-DOSE			
<b>2</b> NDC:36987-2043-2	10 mL in 1 VIAL, MULTI-DOSE			
<b>3</b> NDC:36987-2043-3	30 mL in 1 VIAL, MULTI-DOSE			
4 NDC:36987-2043-4	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	

penicillium notatum injection, so	olution				
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Ite m	Code (Source)	NDC:369	87-2052
Route of Administration	SUBCUTANEOUS, INTRADERMAL				
Active Ingredient/Active M	Ioiety				
I	ngredient Name		Basis of Stre	ength	Strengt
	A <b>R. CHRYSOGENUM</b> (UNII: 3Y1PE1GCIG) R. CHRYSOGENUM - UNII:3Y1PE1GCIG)		PENICILLIUM CHRY VAR. CHRYSOGEN		0.05 g in 1 mL
Inactive Ingredients					
	Ingredient Name			Stren	ıgth
	MDF5V39QO)				
SODIUM BICARBONATE (UNII: 81					
	/IQ8X)				
SODIUM CHLORIDE (UNII: 451W4	/1Q8X)				
SODIUM BICARBONATE (UNII: 81 SODIUM CHLORIDE (UNII: 451W4 PHENOL (UNII: 339NCG44TV) WATER (UNII: 059QF0K00R)	/1Q6A)				

Р	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:36987-2052-1	5 mL in 1 VIAL, MULTI-DOSE						
2	NDC:36987-2052-2	10 mL in 1 VIAL, MULTI-DOSE						
3	NDC:36987-2052-3	30 mL in 1 VIAL, MULTI-DOSE						
4	NDC:36987-2052-4	50 mL in 1 VIAL, MULTI-DOSE						

	rmation		<b></b>			34.3.4	
Marketing Category		on Number or Monograph C			ing Start Dat	e Marketir	ng End Date
BLA	BLA102192			08/29/197	72		
AUREOBASIDI	UM PUL	LULANS					
ureobasidium pullular	ns injection,	solution					
Product Information	on						
Product Type		HUMAN PRESCRIPTION DRU	G	Ite m C	ode (Source	) NDC:36	5987-2070
Route of Administrati	on	SUBCUTANEOUS, INTRADE	RMAL				
Active Ingredient/	Active Moi	ety					
	Ing	redient Name			Basis of	Strength	Strength
		<b>. PULLUTANS</b> (UNII: D1A2NG PULLUTANS - UNII:D1A2NG69	/		AUREOBASID PULLULANS PULLUTANS		0.05 g in 1 mL
Inactive Ingredien	ts						
Inactive Ingredien	ts	Ingredient Name				Str	ength
SO DIUM CHLO RIDE (U	JNII: 451W47IQ	8X)				Str	ength
SO DIUM CHLO RIDE (U SO DIUM BICARBO NAT	JNII: 451W47IQ Γ <b>Ε</b> (UNII: 8MDF	8X)				Str	ength
SODIUM CHLORIDE (U SODIUM BICARBONAT PHENOL (UNII: 339NCG	JNII: 451W47IQ F <b>E</b> (UNII: 8MDF 644TV)	8X)				Str	ength
Inactive Ingredien SODIUM CHLORIDE (U SODIUM BICARBONAT PHENOL (UNII: 339NCG WATER (UNII: 059QF0K	INII: 451W47IQ FE (UNII: 8 MDF 44TV) CO0R)	8X)				Str	ength
SO DIUM CHLO RIDE (U SO DIUM BICARBO NAT PHENOL (UNII: 339NCG WATER (UNII: 059QF0K	INII: 451W47IQ FE (UNII: 8 MDF 44TV) CO0R)	8X)				Str	eng th
SO DIUM CHLO RIDE (U SO DIUM BICARBO NAT PHENOL (UNII: 339 NCG WATER (UNII: 059 QF0 K GLYCERIN (UNII: PDC6)	INII: 451W47IQ FE (UNII: 8 MDF 44TV) CO0R)	8X)				Str	ength
SO DIUM CHLO RIDE (U SO DIUM BICARBO NAT PHENOL (UNII: 339 NCG WATER (UNII: 059 QF0 K GLYCERIN (UNII: PDC6) Packaging # Item Code	INII: 451W47IQ FE (UNII: 8 MDF 644TV) 600R) A3C0OX) Pa	8X) 75V39QO) ckage Description	Marketi	ing Star	t Date	Marketing	
SODIUM CHLORIDE (U SODIUM BICARBONAT PHENOL (UNII: 339NCG WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6) Packaging # Item Code 1 NDC:36987-2070-1	UNII: 451W47IQ FE (UNII: 8 MDF 44TV) KO0 R) A3C0 OX) <b>Pa</b> 5 mL in 1 V	8 X) 75 V39 QO) <b>ckage Description</b> VIAL, MULTI-DOSE	Marketi	ing Star	t Date		
SO DIUM CHLO RIDE (U SO DIUM BICARBO NAT PHENOL (UNII: 339NCG WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6) Packaging # Item Code 1 NDC:36987-2070-1 NDC:36987-2070-2	INII: 451W47IQ FE (UNII: 8 MDF 644TV) 600 R) A3C00X) A3C00X) 5 mL in 1 V 10 mL in 1	8 X) 5 V39QO) ckage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ing Star	t Date		
SO DIUM CHLO RIDE (U SO DIUM BICARBO NAT PHENOL (UNII: 339 NCG WATER (UNII: 059 QF0 K GLYCERIN (UNII: PDC6) Packaging # Item Code 1 NDC:36987-2070-1 2 NDC:36987-2070-2 3 NDC:36987-2070-3	INII: 451W47IQ FE (UNII: 8 MDF 44TV) A3C00X) A3C00X) 5 mL in 1 10 mL in 1 30 mL in 1	8 X) 5 V39QO) <b>ckage Description</b> VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ing Star	t Date		
SODIUM CHLORIDE (U SODIUM BICARBONAT PHENOL (UNII: 339 NCG WATER (UNII: 059 QF0 K GLYCERIN (UNII: PDC6 Packaging	INII: 451W47IQ FE (UNII: 8 MDF 44TV) A3C00X) A3C00X) 5 mL in 1 10 mL in 1 30 mL in 1	8 X) 5 V39QO) ckage Description VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ing Star	t Date		
SODIUM CHLORIDE (U SODIUM BICARBONAT PHENOL (UNII: 339NCG WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6 <b>Backaging</b> <b>H</b> Item Code 1 NDC:36987-2070-1 2 NDC:36987-2070-3 4 NDC:36987-2070-4	INII: 451W47IQ FE (UNII: 8 MDF 44TV) A3C00X) A3C00X) 5 mL in 1 5 mL in 1 30 mL in 1 50 mL in 1	8 X) 5 V39QO) <b>ckage Description</b> VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ing Star	t Date		
SODIUM CHLORIDE (U SODIUM BICARBONAT PHENOL (UNII: 339NCG WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6) Packaging # Item Code 1 NDC:36987-2070-1 2 NDC:36987-2070-3	INII: 451W47IQ TE (UNII: 8 MDF 44TV) COOR) A3COOX) A3COOX) 5 mL in 1 5 mL in 1 10 mL in 1 30 mL in 1 50 mL in 1	8 X) 5 V39QO) <b>ckage Description</b> VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			t Date	Marketing	

# RHIZOPUS ORYZAE

rhizopus oryzae injection, solution

<b>Product Information</b>			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2079
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety							
Ingredient Name	<b>Basis of Strength</b>	Strength					
RHIZOPUS ARRHIZUS VAR. ARRHIZUS (UNII: 8476849N1Y) (RHIZOPUS ARRHIZUS VAR. ARRHIZUS - UNII:8476849N1Y)	RHIZOPUS ARRHIZUS VAR. ARRHIZUS	0.05 g in 1 mL					

# Inactive Ingredients

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

#### Packaging

	0 0			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2079-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2079-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2079-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2079-4	50 mL in 1 VIAL, MULTI-DOSE		

# **Marketing Information**

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

## RHODOTORULA MUCILAGINOSA

rhodotorula mucilaginosa injection, solution

Product Information					
Product T ype	HUMAN PRESCRIPTION DRUG	Item Cod	e (Source)	NDC:369	87-2088
Route of Administration	SUBCUTANEOUS, INTRADERMAL				
Active Ingredient/Active Moi	ety				
Ing	gredient Name		Basis of Str	ength	Strength
<b>RHODOTORULA MUCILAGINOSA</b> (1 MUCILAGINOSA - UNIL62TY3X4N97)	UNII: 62TY3X4N9Z) (RHODOTORULA		RHODOTORULA		0.05 g in 1 mL

Ina	ctive Ingredients	3		
	Strength			
SOI	DIUM BICARBONATE	C(UNII: 8MDF5V39QO)		
SOI	DIUM CHLORIDE (UN	II: 451W47IQ8X)		
PHE	NOL (UNII: 339NCG4	4TV)		
WA	<b>FER</b> (UNII: 059QF0KO	0R)		
<b>CT T</b>				
GLY	CERIN (UNII: PDC6A	3CUUX)		
	cerin (UNII: PDC6A.			
Pao		Package Description	Marketing Start Date	Marketing End Date
Pao #	ckaging		Marketing Start Date	Marketing End Date

**3** NDC:36987-2088-3

4 NDC:36987-2088-4

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

30 mL in 1 VIAL, MULTI-DOSE

50 mL in 1 VIAL, MULTI-DOSE

tion, solution HUMAN PRESCRIPTION DRUG				
HUMAN PRESCRIPTION DRUG				
HUMAN PRESCRIPTION DRUG				
HUMAN PRESCRIPTION DRUG				
HOMENI HEBORIN HON DROG	Item Coc	le (Source)	NDC:36	987-2097
SUBCUTANEOUS, INTRADERMAL				
•				
•				
ngredient Name		Basis of Str	ength	Strengt
UNII: 978D8U419H) (SACCHAROMYCES CER			ES	0.05 g in 1 mL
Ingredient Name			Stre	ength
IQ8X)				
DF5V39QO)				
[ ]	<b>oiety</b> I <b>ngredient Name</b> UNII: 978D8U419H) (SACCHAROMYCES CERI	oiety Ingredient Name UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE - Ingredient Name	Soiety       Basis of Structure         Ingredient Name       Basis of Structure         UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE -       SACCHAROMYCES CEREVISIAE -         SACCHAROMYCES CEREVISIAE       SACCHAROMYCES CEREVISIAE -         Ingredient Name       VIQ8X)	Ingredient Name       Basis of Strength         UNII: 978D8U419H) (SACCHAROMYCES CEREVISIAE -       SACCHAROMYCES         CEREVISIAE       SACCHAROMYCES         Ingredient Name       Stree         YIQ8X)       Stree

P	ackaging				
#	Item Code	Package Description	Marke	ting Start Date	Marketing End Date
1	NDC:36987-2097-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-2097-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-2097-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-2097-4	50 mL in 1 VIAL, MULTI-DOSE			
N	Iarketing Inform	mation			
N	Iarketing Category	Application Number or Monograph	Citation	Marketing Start Dat	e Marketing End Date
BI	LA B	3LA102192		08/29/1972	

temphylium sarcinifor	ms injection, solution					
<b>Product Informatio</b>	n					
Product T ype	HUMAN PRESCRIPTION I	HUMAN PRESCRIPTION DRUG Item Code (Source)			NDC:36987-2115	
Route of Administratio	n INTRADERMAL, SUBCUT	TANEOUS				
Active Ingredient/A	ctive Moiety					
	Ingredient Name			Basis of	Strength	Strengt
	IFORME (UNII: XQ14H1462M) (STEMPH	IYLIUM SARCINI	FORME -	STEMPHYLI		0.05 g
UNII:XQ14H1462M)				SARCINIFOF	RME	in 1 mL
Inactive Ingredient	s					
	Ingredient Name				Str	ength
SO DIUM BICARBO NATI						8
SODIUM CHLORIDE (UN						
PHENOL (UNII: 339NCG4	4TV)					
WATER (UNII: 059QF0K	00R)					
GLYCERIN (UNII: PDC6A	3C0OX)					
Packaging						
# Item Code	Package Description	Marketin	g Start	Date	Marketing	End Date
NDC:36987-2115-1	5 mL in 1 VIAL, MULTI-DOSE					
<b>2</b> NDC:36987-2115-2	10 mL in 1 VIAL, MULTI-DOSE					
<b>B</b> NDC:36987-2115-3	30 mL in 1 VIAL, MULTI-DOSE					
NDC:36987-2115-4	50 mL in 1 VIAL, MULTI-DOSE					
Marketing Infor	mation					

08/29/1972

TRICHODERM	A HARZ	IANAM						
trichoderma harzianan	n injection, s	olution						
<b>Product Information</b>	on							
Product Type		HUMAN PRESCRIPTION DR	UG	Item Co	de (Sourc	e)	NDC:30	6987-2124
Route of Administration	on	SUBCUTANEOUS, INTRAD	ERMAL					
Active Ingredient/	Active Moi	ety						
	Ing	gredient Name			Basis o	of Strei	ngth	Strength
	ANUM (UNII: (	CA33Q4013Q) (TRICHODERN	IA HARZIANUI	- N	TRICHODI			0.05 g
UNII:CA33Q4013Q)					HARZIANU	UM		in 1 mL
Inactive Ingredien	te							
macuve mgreuten		Ingredient Name					Str	ength
SODIUM CHLORIDE (U	NII: 451W47IO	-					511	engtn
SO DIUM BICARBONAT								
PHENOL (UNII: 339NCG								
WATER (UNII: 059QF0K	(O0R)							
GLYCERIN (UNII: PDC6)	A3C0OX)							
Packaging								
# Item Code	Pac	ckage Description	Marketin	ng Start I	Date	Mark	eting	End Date
1 NDC:36987-2124-1	5 mL in 1 V	IAL, MULTI-DOSE						
<b>2</b> NDC:36987-2124-2	10 mL in 1	VIAL, MULTI-DOSE						
<b>3</b> NDC:36987-2124-3	30 mL in 1	VIAL, MULTI-DOSE						
4 NDC:36987-2124-4	50 mL in 1	VIAL, MULTI-DOSE						
<b>Marketing Info</b>	rmation							
Marketing Category	Applicatio	on Number or Monograph	Citation 1	Marketing	g Start Da	te Ma	arketin	ng End Date
BLA	BLA102192		0	8/29/1972				
TRICHOPHYT	ON MEN	TAGROPHYTES						
trichophyton mentagro	ophytes injec	ction, solution						
Product Information	on							
Product Type		HUMAN PRESCRIPTION DR	UG	Item Co.	de (Sourc	e)	NDC:30	6987-2133
	<b>a p</b>			item co		,		
Route of Administrati	on	SUBCUTANEOUS, INTRAD	EKMAL					

		ety					
	Ing	redient Name			Basis of S	trength	Strength
<b>TRICHO PHYTO N MENT</b> MENTAGROPHYTES - UN		<b>ES</b> (UNII: 19917J3JIV) (TRICH	OPHYTON		AICHOPHYTOI ENTAGROPHY		0.05 g in 1 mL
Inactive Ingredien	ts						
		Ingredient Name				St	trength
SODIUM BICARBONAT	E (UNII: 8 MDF	75V39QO)					
SODIUM CHLORIDE (U	NII: 451W47IQ	8 X)					
PHENOL (UNII: 339NCG	44TV)						
WATER (UNII: 059QF0K	.00R)						
GLYCERIN (UNII: PDC64	A3C0OX)						
Packaging							
# Item Code	Pao	ckage Description	Marketi	ng Start Da	ate M	larketing	g End Date
<b>1</b> NDC:36987-2133-1	5 mL in 1 V	IAL, MULTI-DOSE					
<b>2</b> NDC:36987-2133-2	10 mL in 1	VIAL, MULTI-DOSE					
<b>3</b> NDC:36987-2133-3	30 mL in 1	VIAL, MULTI-DOSE					
4 NDC:36987-2133-4	50 mL in 1	VIAL, MULTI-DOSE					
Marketing Info	rmation						
Marketing Category	Applicatio	on Number or Monograph	Citation	Marketing	Start Date	Market	ing End Date
	<b>Applicatio</b> BLA102192	on Number or Monograph		<b>Marketing</b> )8/29/1972	Start Date	Market	ing End Date
BLA		on Number or Monograph		0	Start Date	Market	ing End Date
BLA CORN SMUT	BLA102192	on Number or Monograph		0	Start Date	Market	ing End Date
CORN SMUT	BLA102192	on Number or Monograph		0	Start Date	Market	ing End Date
BLA CORN SMUT corn smut injection, so	BLA102192	on Number or Monograph		0	Start Date	Market	ing End Date
BLA CORN SMUT corn smut injection, so Product Informatio	BLA102192	on Number or Monograph		08/29/1972	Start Date		t <b>ing End Date</b>
BLA CORN SMUT corn smut injection, sc Product Informatic Product Type	BLA102192		UG	08/29/1972			
BLA CORN SMUT corn smut injection, sc Product Informatic Product Type	BLA102192	HUMAN PRESCRIPTION DR	UG	08/29/1972			
BLA CORN SMUT corn smut injection, sc Product Informatio Product Type Route of Administratio	BLA102192 Diution	HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD	UG	08/29/1972			
BLA CORN SMUT corn smut injection, sc Product Informatic Product Type	BLA102192 Dolution On Active Moi	HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD	UG	)8/29/1972		NDC	
BLA CORN SMUT corn smut injection, so Product Informatio Product Type Route of Administratio Active Ingredient/A	BLA102192 Dution On Active Moi In	HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD	UG	08/29/1972	e (Source)	NDC:	:36987-2151 Strength
BLA CORN SMUT corn smut injection, so Product Informatio Product Type Route of Administratio Active Ingredient/A USTILAGO MAYDIS (UI	BLA102192 Dolution On Active Moi In; NII: 4K7Z7K7S	HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD ety gredient Name	UG	08/29/1972	e (Source) Basis of Str	NDC:	:36987-2151 Strength
BLA CORN SMUT corn smut injection, so Product Informatio Product Type Route of Administratio Active Ingredient/A	BLA102192 Dolution On Active Moi In; NII: 4K7Z7K7S	HUMAN PRESCRIPTION DR SUBCUTANEOUS, INTRAD ety gredient Name	UG	08/29/1972	e (Source) Basis of Str	NDC: rength AYDIS	:36987-2151

SODIUM CHLORIDE (UNII: 451W47IQ8X)

W	ATER (UNII: 059QF0K	O0R)			
GL	<b>YCERIN</b> (UNII: PDC6 A	A3C0OX)			
Pa	ackaging				
#	Item Code	Package Description	Marke	ting Start Date	Marketing End Date
1	NDC:36987-2151-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-2151-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-2151-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-2151-4	50 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-2151-4	50 mL in 1 VIAL, MOLTI-DOSE			
М	larketing Info	rmation			

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

# OAT SMUT

oat smut injection, solution

Product Information			
Product T ype	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-2160
Route of Administration	SUBCUTANEOUS, INTRADERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
USTILAGO AVENAE (UNII: YIH315U1TU) (USTILAGO AVENAE - UNII:YIH315U1TU)	USTILAGO AVENAE	$0.05\;g$ in $1mL$

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36987-2160-1	5 mL in 1 VIAL, MULTI-DOSE		
2	NDC:36987-2160-2	10 mL in 1 VIAL, MULTI-DOSE		
3	NDC:36987-2160-3	30 mL in 1 VIAL, MULTI-DOSE		
4	NDC:36987-2160-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Info	rmation					
Marketing Category		on Number or Monograph Cita	tion 1	Marketing Start D	ate Ma	rketing End Dat
BLA	BLA102192		0	8/29/1972		
WHEAT SMUT wheat smut injection,						
Product Information	on					
Product Type		HUMAN PRESCRIPTION DRUG		Item Code (Sour	ce)	NDC:36987-2169
Route of Administrati	on	SUBCUTANEOUS, INTRADERM	AL			
Active Ingredient/	Active Moi	ety				
	Ing	gredient Name		Basis o	f Streng	th Strength
	NII: BV820L2I	Z8) (USTILAGO TRITICI - UNII:BV	820L2IZ	USTILAG	O TRITIC	0.05 g in 1 m
Inactive Ingredien	ts					
		Ingredient Name				Strength
SO DIUM BICARBONAT SO DIUM CHLO RIDE (U						
PHENOL (UNII: 339NCG						
WATER (UNII: 059QF0K						
GLYCERIN (UNII: PDC6	A3C0OX)					
Packaging						
# Item Code	Pa	ckage Description	Marketii	ng Start Date	Mark	eting End Date
1 NDC:36987-2169-1	5 mL in 1 \	/IAL, MULTI-DOSE				
<b>2</b> NDC:36987-2169-2		VIAL, MULTI-DOSE				
<b>3</b> NDC:36987-2169-3		VIAL, MULTI-DOSE				
4 NDC:36987-2169-4	50 mL in 1	VIAL, MULTI-DOSE				
_						
Marketing Info	rmation					
Marketing Info Marketing Category		on Number or Monograph Cita	tion 1	Marketing Start D	ate Ma	rketing End Dat

WHEAT BUNT	
wheat bunt injection, solution	

	on						
Product T ype		HUMAN PRESCRIPTION DRU	JG	Ite m Co	de (Source)	ND	C:36987-2178
Route of Administrati	on	INTRADERMAL, SUBCUTAN	NEOUS				
Active Ingredient/		5					
	0	redient Name			Basis of Str	-	Strength
TILLETIA CARIES (UN)	II: C7000B9PQ	I) (TILLETIA CARIES - UNII:C	7000B9PQI)		TILLETIA CAF	RIES	0.05 g in 1 mI
Inactive Ingredien	ts						
		Ingredient Name					Strength
SODIUM BICARBONAT	TE (UNII: 8 MDF	75V39QO)					
SODIUM CHLORIDE (U	NII: 451W47IQ	8X)					
<b>PHENOL</b> (UNII: 339NCG	644TV)						
WATER (UNII: 059QF0K	(O0R)						
GLYCERIN (UNII: PDC6)	A3C0OX)						
Packaging							
	Pac	ckage Description	Marketi	ng Start	Date I	Marketi	ng End Date
# Item Code		r <b>kage Description</b> TAL, MULTI-DOSE	Marketi	ng Start	Date I	Marketi	ng End Date
Item Code           NDC:36987-2178-1	5 mL in 1 V	•	Marketi	ng Start	Date I	Marketi	ng End Date
Item Code           NDC:36987-2178-1           NDC:36987-2178-2	5 mL in 1 V 10 mL in 1	IAL, MULTI-DOSE	Marketi	ng Start	Date I	Marketi	ng End Date
Provide a straig strai	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start	Date I	Marketi	ng End Date
<ul> <li># Item Code</li> <li>1 NDC:36987-2178-1</li> <li>2 NDC:36987-2178-2</li> <li>3 NDC:36987-2178-3</li> </ul>	5 mL in 1 V 10 mL in 1 30 mL in 1	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Start	Date I	Marketi	ng End Date
<ul> <li># Item Code</li> <li>1 NDC:36987-2178-1</li> <li>2 NDC:36987-2178-2</li> <li>3 NDC:36987-2178-3</li> <li>4 NDC:36987-2178-4</li> </ul>	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		ng Start	Date I	Marketi	ng End Date
<ul> <li># Item Code</li> <li>1 NDC:36987-2178-1</li> <li>2 NDC:36987-2178-2</li> <li>3 NDC:36987-2178-3</li> <li>4 NDC:36987-2178-4</li> </ul>	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			Date I		
<ul> <li># Item Code</li> <li>1 NDC:36987-2178-1</li> <li>2 NDC:36987-2178-2</li> <li>3 NDC:36987-2178-3</li> <li>4 NDC:36987-2178-4</li> </ul>	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		ng Start Date		ng End Date eting End Dat
#       Item Code         1       NDC:36987-2178-1         2       NDC:36987-2178-2         3       NDC:36987-2178-3         4       NDC:36987-2178-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 <b>rmation</b> Applicatio	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marketin	ng Start Date		
<ul> <li># Item Code</li> <li>1 NDC:36987-2178-1</li> <li>2 NDC:36987-2178-2</li> <li>3 NDC:36987-2178-3</li> <li>4 NDC:36987-2178-4</li> </ul> Marketing Info Marketing Category BLA	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 <b>rmation</b> Applicatio BLA102192	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Citation	Marketin	ng Start Date		
#       Item Code         1       NDC:36987-2178-1         2       NDC:36987-2178-2         3       NDC:36987-2178-3         4       NDC:36987-2178-4    Warketing Info Marketing Category BLA WHEAT STEM	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 to n to n to n to n to n to n to n to n	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE On Number or Monograph	Citation	Marketin	ng Start Date		
#       Item Code         1       NDC:36987-2178-1         2       NDC:36987-2178-2         3       NDC:36987-2178-3         4       NDC:36987-2178-4	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1 to n to n to n to n to n to n to n to n	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE On Number or Monograph	Citation	Marketin	ng Start Date		
#       Item Code         1       NDC:36987-2178-1         2       NDC:36987-2178-2         3       NDC:36987-2178-3         4       NDC:36987-2178-4    Warketing Info Marketing Category BLA WHEAT STEM	5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1 <b>rmation</b> Applicatio BLA102192 <b>RUST</b> ion, solution	VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE On Number or Monograph	Citation	Marketin	ng Start Date		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
PUCCINIA GRAMINIS (UNII: 00HJ02QBWN) (PUCCINIA GRAMINIS - UNII:00HJ02QBWN)	PUCCINIA GRAMINIS	0.05 g in $1 mL$

SUBCUTANEOUS, INTRADERMAL

Route of Administration

	Ingredient Name			Strength
SODIUM CHLORIDE (U	- INII: 451W47IQ8X)			
SODIUM BICARBONAT	FE (UNII: 8 MDF5V39QO)			
PHENOL (UNII: 339 NCC	644TV)			
WATER (UNII: 059QF0F	(O0R)			
GLYCERIN (UNII: PDC6	A3C0OX)			
Packaging				
# Item Code	Package Description	Market	ing Start Date	Marketing End Date
# Item Code	rackage Description	ivitii iic c	ing Start Date	Marketing Life Date
	5 mL in 1 VIAL, MULTI-DOSE	TVMIT ICC C		Marketing Life Date
1 NDC:36987-2187-1				Min Keting Lift Dute
I         NDC:36987-2187-1           Z         NDC:36987-2187-2	5 mL in 1 VIAL, MULTI-DOSE			in the ting Life Date
NDC:36987-2187-1           NDC:36987-2187-2           NDC:36987-2187-3	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE			Min Keting Lind Dute
I         NDC:36987-2187-1           Z         NDC:36987-2187-2           3         NDC:36987-2187-3	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE			
I         NDC:36987-2187-1           Z         NDC:36987-2187-2           3         NDC:36987-2187-3	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE			
<ul> <li><i>i</i> Item Code</li> <li>NDC:36987-2187-1</li> <li>NDC:36987-2187-2</li> <li>NDC:36987-2187-3</li> <li>NDC:36987-2187-4</li> </ul>	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			
<ol> <li>NDC:36987-2187-1</li> <li>NDC:36987-2187-2</li> <li>NDC:36987-2187-3</li> <li>NDC:36987-2187-3</li> <li>NDC:36987-2187-4</li> </ol>	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 Start Date	

CURVULARIA INEQUA					
1 9 .					
Product Information					
Product T ype	HUMAN PRESCRIPTION DRUG	Item Coo	le (Source)	NDC:36	5987-1962
Route of Administration	SUBCUTANEOUS, INTRADERMAL				
Active Ingredient/Active Mo	iety				
I	ngredient Name		Basis of Stre	ength	Strength
C <b>URVULARIA INAEQUALIS</b> (UNII: W UNII:W042YAB8JC)	V042YAB8JC) (CURVULARIA INAEQUALIS -		CURVULARIA INAEQUALIS		0.05 g in 1 mL
nactive Ingredients					
	Ingredient Name			Str	ength
<b>ODIUM BICARBONATE</b> (UNII: 8 MI	9F5V39QO)				
ODIUM CHLORIDE (UNII: 451W4710	Q8X)				
HENOL (UNII: 339NCG44TV)					
VATER (UNII: 059QF0KO0R)					
GLYCERIN (UNII: PDC6A3C0OX)					
Packaging					

#	Item Code	Package Description	Marke	ting Start Date	Marketing End Date
1	NDC:36987-1962-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-1962-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-1962-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-1962-4	50 mL in 1 VIAL, MULTI-DOSE			
N	larketing Inform	nation			
	larketing Category	Application Number or Monograph	Citation	Marketing Start Da	te Marketing End Date
	lai keung Gategory			-	-
BL		SLA102192		08/29/1972	
		sLA102192		08/29/1972	
		SLA102192		08/29/1972	
BI				08/29/1972	
BI	.A E	IPACTUM	_	08/29/1972	

Product Information					
Product T ype	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1980		
Route of Administration	SUBCUTANEOUS, INTRADERMAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>FUSARIUM COMPACTUM</b> (UNII: V4OQR60A5P) (FUSARIUM COMPACTUM - UNII:V4OQR60A5P)	FUSARIUM COMPACTUM	0.05 g in 1 mL		

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

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36987-1980-1	5 mL in 1 VIAL, MULTI-DOSE			
2	NDC:36987-1980-2	10 mL in 1 VIAL, MULTI-DOSE			
3	NDC:36987-1980-3	30 mL in 1 VIAL, MULTI-DOSE			
4	NDC:36987-1980-4	50 mL in 1 VIAL, MULTI-DOSE			

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

Product Inforn							
	nation						
Product T ype		HUMAN PRESCRIPTION DRUG Item Code (Source)			NDC:36987-2061		
Route of Administ	tration						
Active Ingredie							
		gredient Name			Basis of St	-	Strength
PHO MA GLO MERA	ATA (UNII: UPX000	VMIF) (PHOMA GLOMERATA -	- UNII:UPX00	0 VMIF)	PHOMA GLOI	MERATA	0.05 g in 1 m
Inactive Ingred	lients						
		Ingredient Name				S	trength
SO DIUM BICARBO	NATE (UNII: 8 MDI	F5V39QO)					
SODIUM CHLORID	<b>)E</b> (UNII: 451W47IQ	8X)					
PHENOL (UNII: 339	NCG44TV)						
WATER (UNII: 0590	F0KO0R)						
GLYCERIN (UNII: P	DC6A3C0OX)						
Packaging			Marketir	ng Start D	ate M	larketing	Find Date
f Item Cod	e Pa	ckage Description					5 Life Date
		VIAL, MULTI-DOSE					5 Life Dute
f Item Cod	-1 5 mL in 1 V						5 Liiu Dutt
Item Cod           NDC:36987-2061	-1 5 mL in 1 V -2 10 mL in 1	VIAL, MULTI-DOSE					5 Linu Dutt

Labeler - Nelco Laboratories, Inc. (054980867)

Registrant - Nelco Laboratories, Inc. (054980867)

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