FOOD - PLANT SOURCE, YEAST, BAKER SACCHAROMYCES CEREVISIAE- yeast, baker saccharomyces cerevisiae injection, solution FOOD - PLANT SOURCE, YEAST, BREWER SACCHAROMYCES CEREVISIAE- yeast, brewer saccharomyces cerevisiae injection, solution INSECTS WHOLE BODY COCKROACH MIX- insects whole body cockroach mix injection, solution **INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS INVICTA- ant, fire solenopsis** invicta injection, solution **INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS RICHTERI- ant, fire solenopsis** richteri injection, solution INSECTS WHOLE BODY, FIRE ANT MIX- insects whole body, fire ant mix injection, solution MOLDS - ALTERNARIA/HORMODENDRUM MIX- molds - alternaria/hormodendrum mix injection, solution MOLDS - MOLD MIX 10- molds - mold mix 10 injection, solution MOLDS - MOLD MIX 4- molds - mold mix 4 injection, solution MOLDS - TRICHOPHYTON MIX- molds - trichophyton mix injection, solution MOLDS, PENICILLIUM MIX- molds, penicillium mix injection, solution MOLDS, RUSTS AND SMUTS, ALTERNARIA TENUIS- alternaria tenuis injection, solution MOLDS, RUSTS AND SMUTS, ASPERGILLUS FUMIGATUS- aspergillus fumigatus injection, solution MOLDS, RUSTS AND SMUTS, ASPERGILLUS NIGER- aspergillus niger injection, solution MOLDS, RUSTS AND SMUTS, BOTRYTIS CINEREA- botrytis cinerea injection, solution Jubilant Hollis terStier LLC

INSTRUCTIONS ALLERGENIC EXTRACTS FOR SCRATCH, PRICK OR PUNCTURE TESTING

WARNINGS

This product is intended for use only by licensed medical personnel experienced in administering allergenic extracts and trained to provide immediate emergency treatment in the event of a life-threatening reaction. Allergenic extracts may potentially elicit a severe life threatening systemic reaction, rarely resulting in death.7 Therefore, emergency measures and personnel trained in their use must be available immediately in the event of such a reaction. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician's office if symptoms occur. 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. This product should never be injected intravenously. Refer also to the WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS Sections for further discussion.

DESCRIPTION

Sterile extracts for scratch, prick or puncture testing are supplied in dropper vials containing, in addition to the extract allergens and antigens, 50% (v/v) glycerin as preservative, 0.5% sodium chloride and 0.275% sodium bicarbonate. The strength of these extracts may be expressed in terms of

- Weight to Volume (w/v)
- Protein Nitrogen Units/mL (PNU/mL)
- Amb a 1 Units/mL (Amb a 1/mL)
- Allergy Units/mL (AU/mL)
- Bioequivalent Allergy Units/mL (BAU/mL)
- Concentrate

1. Weight to volume (w/v).

For regular extracts this describes the extraction ratio, i.e., the amount of crude allergen added to the extracting fluid. A 1:10 extract, therefore, indicates that the solution contains the extracted material from one gram of raw material added to each 10 mL of extracting fluid. The amount and composition of extracted materials will vary with the kind of antigen, the extracting fluid, duration of extraction, pH, temperature, and other variables. APTM (acetone precipitated) extracts, if present, are prepared by reconstituting dry, allergenically active concentrates produced by precipitation process from extracts of raw materials. For those APTM extracts labeled on a weight per volume (w/v) basis, the strength designation indicates the dry weight of finished (acetone) precipitate per volume of reconstituting fluid. For example, 1:50 (w/v) means that each gram of dry precipitate obtained from the original extract is reconstituted in 50 mL of solution.

2. Protein Nitrogen Units per mL (PNU/mL).

One protein nitrogen unit represents 0.00001 mg phosphotungstic acid-precipitable protein nitrogen dissolved in one mL of antigen extract. The PNU content of extracts of the same antigen may vary according to the method of measuring the PNU. Thus, the PNU content of extracts from different manufacturers is not comparable unless the PNU method is known to be the same and reproducible from lot to lot. Also, the amount of protein nitrogen extracted from an antigen is influenced by the same variables as the weight to volume extract. Allergenic materials make up a variable proportion of the total protein of an extract.

3. Amb a 1. Of the many allergens which have been purified and characterized from Short Ragweed (Amb a 1¹², Amb a 2¹³, Ra3¹⁴, Ra4(BPA-R)¹⁵, Ra5¹⁶, Ra6, Ra7, and Ra8¹⁷, and cytochrome C¹⁸), Amb a 1 (also known as Antigen E) is considered the most important and has been selected as the basis for standardization. Extracts of Short Ragweed containing Amb a 1 are diffused in agar against standard antiserum to Amb a 1, and compared to the diffusion of standard Amb a 1 solutions. The amount of Amb a 1 is expressed as units of Amb a 1 per mL of extract.

If an extract is diluted with a diluent or other allergenic extracts, the Amb a 1 concentration must be determined by calculation.

4. Allergy Units per mL (AU/mL).

The potency of extracts labeled in Allergy Units per mL (AU/mL) is determined by in vitro comparison to a reference standard established by the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA).

5. Bioequivalent Allergy Units per mL (BAU/mL).

When originally licensed, the Reference Preparations for standardized extracts were arbitrarily assigned 100,000 Allergy Units (AU)/mL. Subsequently, quantitative skin testing by the ID₅₀EAL method 13 was used to determine that some Reference Preparations should be assigned 10,000 AU/mL, and others 100,000 AU/mL. To avoid possible confusion about this change in the method of allergy unit assignment, the nomenclature changed for standardized extracts whose allergy units are assigned based on quantitative skin testing, and such products are labeled in Bioequivalent Allergy Units (BAU)/mL. References labeled 10,000 BAU/mL can be diluted one to a half million fold, and references labeled 100,000 BAU/mL can be diluted one to 5 million fold and produce a sum of erythema diameter of 50 mm when Intradermal testing highly reactive subjects.

6. Concentrate.

Concentrate label terminology applies to allergenic extract mixtures, where the individual allergens being combined vary in strength or the designation of strength.

CLINICAL PHARMACOLOGY

Allergenic extracts for scratch, prick or puncture testing, used according to the DOSAGE AND ADMINISTRATION section, produce erythema or erythema and wheal reactions in patients with

significant IgE-mediated sensitivity to the relevant allergen. This allergic inflammatory response, although not completely understood, is thought to begin with reaction of antigen with IgE on the surface of basophils or mast cells, which initiates a series of biochemical events resulting in the production of histamine and other mediators. These, in turn, produce the immediate-type "wheal and flare" skin reaction.

INDICATIONS & USAGE

Certain diagnostics carry labeling which states **Allergenic Extract for Diagnostic Use Only**. Data to support the therapeutic use of products labeled with this statement have not been established. 14 In addition to a carefully taken history, the use of glycerin-containing extracts in scratch, prick or puncture testing is an accepted method in the diagnosis of allergic conditions. 1, 2, 3 Extracts of all allergens do not produce equivalent results in scratch, prick or puncture tests. The intensity of the skin reactions produced will be determined by two factors: the degree of sensitivity of the patient, and the nature of the allergenic extract applied.

Scratch, prick or puncture tests are not as sensitive as the intradermal test, but are safer and cause less discomfort. They may, therefore, be the method of choice when a large number of tests are needed, or when testing the pediatric patient. In some cases, where the relatively insensitive scratch, prick or puncture tests are negative or do not confirm the allergic history, follow-up intradermal tests may be positive. However, ANTIGENS PRODUCING LARGE 3 to 4+ SCRATCH, PRICK OR PUNCTURE TESTS SHOULD NOT BE TESTED INTRADERMALLY.

CONTRAINDICATIONS

There are no known absolute contraindications to allergy skin testing. Patients with cardiovascular diseases or pulmonary diseases such as symptomatic asthma, and/or who are receiving cardiovascular drugs such as beta blockers, may be at higher risk for severe adverse reactions. These patients may also be more refractory to the normal anaphylaxis treatment regimen.

WARNINGS

Excessively large local reactions or systemic reactions are more likely to occur if the patient is skin tested shortly after exposure to large amounts of antigen to which s/he is sensitive. Use caution when skin testing patients during a season when pollen is present. Refer to boxed WARNINGS Section.

PRECAUTIONS

1. General

Always have injectable epinephrine and a tourniquet available when tests are being made. (See ADVERSE REACTIONS section.) Generally 50 to 60 scratch, prick or puncture tests can be applied safely at one sitting. Patients whose history suggests severe sensitivity should have only 5 to 10 tests applied at a time and these tests applied to the volar surface of one arm. These tests should not all be of the same type of antigen; that is, all grass pollens, all weed pollens, all danders, etc. One or two tests from several classes of antigens should be applied at a time. As soon as a large wheal begins to develop, wipe the antigen from it with a damp cotton sponge. After 10 minutes wipe off all the antigens with a damp cotton sponge, followed by a dry cotton sponge. Be careful not to wipe antigen from a positive reaction onto an adjacent test site.

2 Information for Patients

Patients should be instructed in the recognition of adverse reactions to diagnostic testing. Patients should be made to understand the importance of a 30 minute observation period, and be warned to return

to the office promptly if symptoms occur after leaving.

3. Drug Interactions

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.6 Certain medications may lessen the skin test wheal and erythema responses elicited by allergens and histamine for varying time periods. Conventional antihistamines should be discontinued at least 5 days before skin testing. Long acting antihistamines should be discontinued for at least 3 weeks prior to skin testing.9 Topical steroids should be discontinued at the skin test site for at least 2-3 weeks before skin testing.9, 10 Tricyclic antidepressants such as Doxepin should be withheld for at least 7 days before skin testing.11 Topical local anesthetics may suppress the flare responses and should be avoided in skin test sites.12

4. Carcinogenesis, mutagenesis, Impairment of Fertility

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

5. Pregnancy

4,5

Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Allergenic extracts should be given to a pregnant woman only if clearly needed.

6. Nursing Mothers

There are no current studies on secretion of the allergenic extract components in human milk or effect on the nursing infant. Because many drugs are excreted in human milk, caution should be exercised when allergenic extracts are administered to a nursing woman.

7. Pediatric Use

Wheal sizes in response to allergen skin testing can be smaller in infants than in adults. The skin response to histamine parallels that for allergens; therefore, appropriate positive control skin tests should always be performed.1

8. Geriatric Use

Skin test wheal size decreases with age. The decrease in allergen-induced skin test reaction parallels that to histamine; therefore, appropriate positive skin test controls should always be performed.1

ADVERSE REACTIONS

1. Local Reactions

If a severe local reaction occurs during scratch, prick or puncture testing, WIPE OFF test antigen. Large, persistent local reactions or minor exacerbations of the patient's allergic symptoms may be treated by local cold applications and/or the use of oral antihistamines, but they should be considered a warning of possible severe systemic reactions.

2. Systemic Reactions

With careful attention to dosage and administration, such reactions occur infrequently, but it must be remembered that allergenic extracts are highly potent in sensitive individuals and OVERDOSE could result in anaphylactic symptoms. Therefore, it is imperative that physicians administering allergenic

extracts understand and be prepared for the treatment of severe reactions.

Adverse reaction frequency data for allergenic extract administration for testing and treatment show that risk is low.7, 8

It cannot be overemphasized that, under certain unpredictable combinations of circumstances, anaphylactic shock is a possibility. Other possible systemic reaction symptoms include fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis and urticaria. **If a systemic or anaphylactic reaction does occur, WIPE OFF test antigen, apply a tourniquet above the site of injection, if tests are performed on the arms, and inject the 1:1,000 epinephrinehydrochloride intramuscularly or subcutaneously into the opposite arm. Loosen the tourniquet at least every 10 minutes. Do not obstruct arterial blood flow with the tourniquet.**

EPINEPHRINE:

ADULT DOSAGE: 0.3 to 0.5 mL should be injected. Repeat in 5 to 10 minutes if necessary. **PEDIATRIC DOSAGE:** The usual initial dose is 0.01 mg (mL) per kg body weight or 0.3 mg (mL) per square meter of body surface area. Suggested dosage for infants to 2 years of age is 0.05 mL to 0.1 mL; for children 2 to 6 years, 0.15 mL; and children 6 to 12 years, 0.2 mL. Single pediatric doses should not exceed 0.3 mg (mL). Doses may be repeated as frequently as every 20 minutes, depending on the severity of the condition and the response of the patient. After administration of epinephrine, profound shock or vasomotor collapse should be treated with intravenous fluids, and other appropriate drugs. Oxygen should be given by mask. Intravenous antihistamine, theophylline or corticosteroids may be used if necessary after adequate epinephrine and circulatory support have been given. Emergency resuscitation measures and personnel trained in their use should be available immediately in the event of a serious systemic or anaphylactic reaction not responsive to the above measures (Ref. J. Allergy Clin. Immunol. 77 (2): 271-273, 1986). Rarely are all of the above measures necessary; the tourniquet and epinephrine usually produce prompt responses. However, the physician should be prepared in advance for all contingencies. Promptness in beginning emergency treatment measures is of utmost importance.

3. Adverse Event Reporting

Report all adverse events to Jubilant HollisterStier LLC Customer Technical Services Department at 1 (800) 992-1120. A voluntary adverse event reporting system for health professionals is available through the FDA MEDWATCH program. Preprinted forms (FDA Form 3500) are available from the FDA by calling 1 (800) FDA-1088. Completed forms should be mailed to MEDWATCH, 5600 Fisher Lane, Rockville, MD 20852-9787 or Fax to: 1 (800) FDA-0178.

OVERDOSAGE

See ADVERSE REACTIONS Section.

DOSAGE & ADMINISTRATION

1. General

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

2. Scratch, Prick or Puncture Testing Methods

There are two general methods of skin testing. (1) The skin is scarified first, and the extract is then applied. (2) A drop of extract is put onto the skin, and a prick or puncture is made through the drop. Avoid touching tip of dropper to skin. Either method is satisfactory, but the second requires that the instrument be cleansed between tests or that separate needles be used.

The extracts for scratch, prick or puncture testing are supplied in dropper vials and should be kept in a rack or box in rows of 10 vials corresponding to the rows of tests to be applied to the skin.

All skin tests should be validated by appropriate positive control tests (e.g., histamine) and negative

control tests (e.g., Glycerin, Albumin Saline with Phenol (0.4%), or Buffered Saline with Phenol). The negative control test should be the same material as is used as a diluting fluid in the tested extracts. Diluting fluid is used in the same way as an active test extract.

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. Delayed reactions may rarely occur from tests, so it may be helpful to examine the test sites in 24 hours.

Use of Scarifiers and Spacing. Make scarifications at least 2.5 cm apart. Use more space between pollen tests to prevent smearing into adjacent sites. Hold the scarifier between the thumb and index finger, press the sharp edge of the instrument against the skin and twirl instrument rapidly. The scratch should disrupt only the outer layers of epidermis but should not produce immediate oozing of blood. The amount of pressure needed to produce a satisfactory scratch will vary between patients according to the thickness or fragility of their skin. Experience will indicate the proper amount of pressure to exert in making the scratch. If the scarifier is kept sharp and the scratch made quickly, discomfort to the patient is minimized.

Use of Prick Test Needles. The skin is cleaned and single drops of each extract applied to the properly identified test sites. A small, sterile disposable needle, such as a 1/2-inch 26 gauge needle (with the bevel up), a bifurcated vaccinating needle, or a Prick Lancetter[™] is inserted through the drop superficially into the skin, the skin lifted slightly and the needle withdrawn. No bleeding should be produced. After about 1 minute the extract may be wiped away.

3. Most Satisfactory Sites for Testing

Prior to testing, clean the skin area to be tested with ether or alcohol and allow to dry. Use a sterile instrument for each patient. The back or the volar surface of the arms are the most satisfactory sites for testing. Skin of the posterior thighs or abdomen may be used if necessary. Avoid very hairy areas where possible, since the reactions will be smaller and more difficult to interpret. The most satisfactory areas of the back 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. The best areas of the arms are the volar surfaces from the axilla to 2.5 or 5 cm above the wrist, skipping the anti-cubital space.

4. Use of Antigen Mixes

The use of complicated mixes of unrelated pollens for testing is not recommended since in the case of a positive reaction, it does not indicate which pollen(s) are responsible, and, in the case of a negative reaction, it fails to indicate whether the individual pollens at full concentration would give a positive reaction.

5. Reading Skin Test Reactions

A positive reaction consists of an urticarial wheal with surrounding erythema (resembling somewhat a mosquito bite reaction) larger than the control site. The smallest reaction considered positive is erythema with a central papule at least 5 mm in diameter. In some instances with no reaction at the control site, erythema may be considered an indication of sensitivity. In general, the size of wheal and erythema response correlates directly with the patient's sensitivity to that allergen.

Standardized Products

(a) Mites:

The skin test concentration of 30,000 AU/mL in dropper vials is used for scratch, prick or puncture testing. Puncture tests performed on 12 highly sensitive subjects showed the following:

Species	Mean Sum of Wheal Mean Sum of Erythema		
species	± Std. Dev. (mm)	± Std. Dev. (mm)	
D. farinae	22.4 ± 10.7	82.2 ± 21.7	
D. pteronyssinus	24.0 ± 9.9	89.3 ± 24.5	

The sum of a skin response is the sum of the longest diameter and the mid-point orthogonal diameter.

(b) Cat Hair and Cat Pelt: The skin test concentration of 10,000 BAU/mL (10-19.9 Fel d 1 Units/mL) in dropper vials is used for prick or puncture testing. Puncture tests performed on 15 highly sensitive subjects showed the following:

Product	Mean Sum of Wheal ± Std. Dev (mm)	Mean Sum of Erythema ± Std. Dev (mm)
Standardized Cat Hair	15.1 ± 3.8	73.3 ± 14.3
Standardized Cat Pelt	13.9 ± 4.3	67.3 ± 13.3

The sum of a skin response is the sum of the longest diameter and the mid-point orthogonal diameter.

(c) **Ragweed pollen** (Short Ragweed or Giant and Short Ragweed Mixture) Antigen E Assayed: Short Ragweed extract at 1:20 w/v in 50% glycerin containing approximately 100 to 300 units of Amb a 1/mL or Giant and Short Ragweed Mix at 1:20 w/v in 50% glycerin containing approximately 50 to 150 units of Amb a 1/mL are usually used for scratch, prick or puncture testing.

Refer to the following table to determine the skin test sensitivity grade. The corresponding $\sum E$ (sum of the longest diameter and the mid-point orthogonal diameters of erythema) is also presented.

Grade	Erythema	Papule or Whea	l Corresponding
Graue	mm	mm	mm ∑E
0	<5	<5	<10
±	5-10	5-10	10-20
1+	11-20	5-10	20-40
2+	21-30	5-10	40-60
3+	31-40	10-15 (a)	60-80
4+	>40	>15 (b)	>80

(a) or with pseudopods (b) or with many pseudopods

A positive skin reaction to any allergen must be interpreted in light of the patient's history of symptoms, time of the year, and known exposures.

THE SKIN TESTS ARE IN NO WAY A SUBSTITUTE FOR A CAREFUL ALLERGIC HISTORY. THEY SERVE AS ADDITIONAL INFORMATION TO AID IN IDENTIFYING CAUSATIVE ALLERGENS IN PATIENTS WITH ALLERGIC DISORDERS.

6. Geriatric Use

The dose is the same in patients of all age groups. Because the wheal size in response to allergen skin testing decreases with age, appropriate histamine positive control skin tests must be performed.1

7. Pediatric Use

The dose is the same in patients of all age groups. Wheal size in response to allergen skin testing can be smaller in infants than in adults. Appropriate histamine positive control skin tests must be performed.1

HOW SUPPLIED

In 5 mL dropper bottles of extract at 1:10 w/v except pollen at 1:20, AP[™] extracts at 1:50 w/v, except AP[™] Dog Hair-Dander at 1:100 w/v, AP[™] House Dust at 20,000 PNU/mL, some mixes as

Concentrate, and Standardized products at AU/mL (Mite extracts at 30,000 AU/mL) or BAU/mL (Cat Hair and Pelt extracts at 10,000 BAU/mL) value. Strengths are listed on product labels.

STORAGE

The expiration date of the diagnostic extracts is listed on the container label. The extract should be stored at 2° - 8°C and kept at this temperature range during office use.

LIMITED WARRANTY

A number of factors beyond our control could reduce the efficacy of this product or even result in an ill effect following its use. These include storage and handling of the product after it leaves our hands, diagnosis, dosage, method of administration, and biological differences in individual patients. Because of these factors, it is important that this product be stored properly, and that the directions be followed carefully during use. No warranty, express or implied, including any warranty of merchantability or fitness, is made. Representatives of the Company are not authorized to vary the terms or the contents of any printed labeling, including the package insert, for this product except by printed notice from the Company's headquarters. The prescriber and user of this product must accept the terms hereof.

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	COCKRO	АСН МІХ	RECORDER OF
reservative: 10% Glycerin v/v nactive Ingredients: 1.5% Sodium chloride 1.275% Sodium icarbonate	50% eac america germa	na, B.	(01)00365044658519 (17)201101 (10)T0000411 (21)00000020101
	1:10 W/V		
tem: 6585ED ot: T0000411 xp: 2020Nov01	No U.S. Standard o Dose/Route: 1 drop 5 mL		NDC: 65044-6585-1 US License No. 1272

Cockroach Mix, 5 mL 1:10 w/v Vial Label

COCKROACH (AMERICAN, GE		9 - H01
50% each of P. america	ana, B. germanica	0000001619
5 mL 1:10 W/V Dose/Route: 1 drop topically	RX Only Sterile Until Opened Store at 2-8°C	- IUI
Preservative 50% Glycerin v/v U.S. License No. 1272	Item: 6585ED Lot: T0000411 Exp: 2020Nov01	1.55100000000

Fire Ant Mix, 5 mL 1:10 w/v Carton Label

ALL	ERGENIC		
Preservative: 50% Glycerin v/v Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate	50% each of S. S. richter		(01)00365044651510 (17)201101 (10)T0000407 (21)00000020051
	1:10 W/V		
ltem: 6515ED Lot: T0000407 Exp: 2020Nov01	No U.S. Standard of Pot Dose/Route: 1 drop topi 5 mL I		NDC: 65044-6515-1 US License No. 1272 5000000649 - H01
Non-Returnable	Store at 2-8°C RX Only Sterile Until Op	ened	50000000649 - HOT

Fire Ant Mix, 5 mL 1:10 w/v Vial Label

SOLE	FIRE ANT N NOPSIS INVICTA		- H01
	% each of S. invi		19000000
5 mL Dose/Route	1:10 W/V e: 1 drop topically	RX Only Sterile Until Opened Store at 2-8°C	1 1 200
	e 50% Glycerin v/v e No. 1272	Item: 6515ED Lot: T0000407 Exp: 2020Nov01	100000000000000000000000000000000000000
Jubila	nt HollisterStier LLC S		

Alternaria Hormodendrum Mix, 5 mL 1:10 w/v Carton Label

Preservative:		Ernaria, Endrum Mix	
0% Glycerin v/v nactive Ingredients: .5% Sodium chloride .275% Sodium icarbonate	alter	ach of A. nata, C. porioides	(01)00365044500313 (17)201101 (10)T0000361 (21)
	1:10 \	N/V	
em: 5003ED ot: T0000361 xp: 2020Nov01	No U.S. Standa Dose/Route: 1		NDC: 65044-5003-1 US License No. 1272
.xp. 2020140401	5 mL	Item: 5003ED	5000000649 - H01
Non-Returnable	Store at 2-8°C RX Only Sterile	Until Opened	50000000099 - HO

Alternaria Hormodendrum Mix, 5 mL 1:10 w/v Vial Label

		DENDRUM MIX DSPORIOIDES)	10H - 61
50%	each of A. a cladosporio		00000026
5 mL Dose/Route: 1 dr	1:10 W/V op topically	RX Only Sterile Until Opened Store at 2-8°C	1011
Preservative 50% U.S. License No.		Item: 5003ED Lot: T0000361 Exp: 2020Nov01	F1000000

Alternaria *tenuis*, 5 mL 1:10 w/v Carton Label

	ALTERNARIA 1	ENUIS	1452/8162/26
Preservative: 50% Glycerin v/v Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate	A. alternat	a	(01)00365044500917 (17)201101 (10)T0000363 (21)00000020051
	1:10 W/V		
ltem: 5009ED Lot: T0000363 Exp: 2020Nov01	No U.S. Standard of Pote Dose/Route: 1 drop topic 5 mL It		NDC: 65044-5009-1 US License No. 1272 50000000649 - H01
Non-Returnable	Store at 2-8°C RX Only Sterile Until Ope	ened	50000000099 - H01

Alternaria *tenuis*, 5 mL 1:10 w/v Vial Label

EXTRACT
nata
RX Only Sterile Until Opened Store at 2-8°C
Item: 5009ED Lot: T0000363 Exp: 2020Nov01

Aspergillus *fumigatus*, 5 mL 1:10 w/v Carton Label

Preservative:	ASPERG FUMIG		
50% Glycerin wv nactive Ingredients: 0.5% Sodium chloride 0.275% Sodium Dicarbonate	A. fumig	atus	(01)00365044502119 (17)201101 (10)T0000365 (21)000000020051
	1:10 W/V		
ltem: 502 1ED Lot: T0000365 Exp: 2020Nov01	No U.S. Standard of Dose/Route: 1 drop 5 mL		NDC: 65044-5021-1 US License No. 1272
Non-Returnable	Store at 2-8°C RX Only Sterile Unti	Opened	5000000649 - H01

Aspergillus *fumigatus*, 5 mL 1:10 w/v Vial Label

ASPERGILLU	S FUMIGATUS
A. fu	nigatus
5 mL 1:10 W Dose/Route: 1 drop topical	Until Unened
Preservative 50% Glycerin U.S. License No. 1272	v/v Item: 5021ED Lot: T0000365 Exp: 2020Nov01

Aspergillus *niger*, 5 mL 1:10 w/v Carton Label

	ASPERGILLUS	NIGER	1462/312226
Preservative: 50% Glycerin v/v			
Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate	A. niger var. r	iger	(01)00365044503314 (17)201101 (10)T0000367 (21)000000020051
	1:10 W/V		
Item: 5033ED Lot: T0000367	No U.S. Standard of Pot Dose/Route: 1 drop topic		NDC: 65044-5033-1
Exp: 2020Nov01	5 mL It	em: 5033ED	US License No. 1272 5000000649 - H01
Non-Returnable	Store at 2-8°C RX Only Sterile Until Ope	ened	50000000099 - H01

Aspergillus *niger*, 5 mL 1:10 w/v Vial Label

ASPERGILLUS	NIGER
A. niger var	. niger
5 mL 1:10 W/V Dose/Route: 1 drop topically	RX Only Sterile Until Opened Store at 2-8°C
Preservative 50% Glycerin v/v U.S. License No. 1272	item: 5033ED Lot: T0000367 Exp: 2020Nov01

Botrytis *cinerea*, 5 mL 1:10 w/v Carton Label

	BOTRYTIS CIN	IEREA	6462/816226
Preservative: 50% Glycerin v/v Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate	B. cinerea	1	(01)00365044504915 (17)201101 (10)T0000369 (21)00000020051
	1:10 W/V		
ltem: 5049ED Lot: T0000369 Exp: 2020Nov01	No U.S. Standard of Pot Dose/Route: 1 drop topi 5 mL I		NDC: 65044-5049-1 US License No. 1272 5000000649 - H01
Non-Returnable	Store at 2-8°C RX Only Sterile Until Op	ened	50000000099 - H01

Botrytis *cinerea*, 5 mL 1:10 w/v Vial Label

AL	LERGENIC BOTRYTIS CIN	EXTRACT	HO1
	B. cinere	ea	- 6192000000
5 mL Dose/Route	1:10 W/V 1 drop topically	RX Only Sterile Until Opened Store at 2-8°C	-H01 50
Preservative U.S. License	50% Glycerin v/v No. 1272	Item: 5049ED Lot: T0000369 Exp: 2020Nov01	000000143
Jubila	nt HollisterStier LLC S		~

Mold Mix #4, 5 mL 1:10 w/v Carton Label

ALL	ERGENIC EXTR	ACT
Preservative: 50% Glycerin v/v Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate	MOLD MIX #4 25% each of A. alternata, C. cladosporoides; 6.2% each of A. fumigatus, A. nidulans, A. niger var. niger, A. terreus, P. digitatum, P. expansum, P. chrysogenum var. chrysogenum, C. rosea f. rosea 1:10 W/V	(01)00365044500214 (17)201101 (10)T0000359 (21)00000020101

Item: 5002ED Lot: T0000359		ard of Potency drop topically	NDC: 65044-5002-1
Exp: 2020Nov01	5 mL	Item: 5002ED	US License No. 1272 5000000649 - H01
Non-Returnable	Store at 2-8°C RX Only Sterile	e Until Opened	
			5000000099 - H

Mold Mix #4, 5 mL 1:10 w/v Vial Label



Mold Mix #10, 5 mL 1:10 w/v Carton Label

ALLERGENIC EXTRACT

MOLD MIX #10

Preservative: 50% Glycerin v/v

Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate 2.5% each of A. fumigatus, A. nidulans, A. niger, A. terreus, P. digitatum, P. expansum, P. chrysogenum, C. rosea f. rosea; 10% each of A. alternata, F. oxysporum vasinfectum, D. vinosa, C. cladosporioides, M. racemosus, P. exigua, A. pullulans, R. stolonifera

1:10 W/V



(01)00365044513719 (17)201101 (10)10000389 (21)00000020051

 Item: 5137ED
 Dose/Route: 1 drop topically
 NDC: 65044-5137-1

 Lot: T0000389
 Dose/Route: 1 drop topically
 US License No. 1272

 Exp: 2020Nov01
 5 mL
 Item: 5137ED
 US License No. 1272

 Store at 2-8°C
 Store at 2-8°C
 RX Only Sterile Until Opened
 s000000099-H01

Mold Mix #10, 5 mL 1:10 w/v Vial Label

. .

		EXTRACT	
1	MOLD MIX	#10	ER.
expansum, P. chrysog oxysporum vasinfect	enum, C. rosea f. rose	100000000000000000000000000000000000000	50000002619
5 mL Dose/Route: 1 dro	1:10 W/V op topically	RX Only Sterile Until Opened Store at 2-8°C	LOH-
Preservative 50% U.S. License No.		Item: 5137ED Lot: T0000389 Exp: 2020Nov01	0H-EF10000000

Penicillium Mix, 5 mL 1:10 w/v Carton Label

Preservative:	PENIC	ILLIUM MIX	
50% Glycerin v/v			
Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate	expansum P. chryso chrysogen	each of P. , P. digitatum, ogenum var. um, C. rosea f. osea	(01)00365044516918 (17)201101 (10)T0000393 (21)000000020001
	1:10	W/V	
tem: 5169ED ot: T0000393	No U.S. Stand Dose/Route: 1	ard of Potency drop topically	NDC: 65044-5169-1
Exp: 2020Nov01	5 mL	Item: 5169ED	US License No. 1272 5000000649 - H01
Non-Returnable	Store at 2-8°C RX Only Sterile	e Until Opened	5000000099 - H01

Penicillium Mix, 5 mL 1:10 w/v Carton Label

PENICILLIUM	M MIX	- MOT
25% each of P. expansu chrysogenum var. chrysoge		000000000000000000000000000000000000000
5 mL 1:10 W/V Dose/Route: 1 drop topically	RX Only Sterile Until Opened Store at 2-8°C	101
Preservative 50% Glycerin v/v U.S. License No. 1272	Item: 5169ED Lot: T0000393 Exp: 2020Nov01	000000143-1

Trichophyton Mix, 5 mL 1:10 w/v Carton Label

ALL	ERGENIC I	EXTR.	ACT
Preservative: 50% Glycerin v/v Inactive Ingredients: 0.5% Sodium chloride 0.275% Sodium bicarbonate	TRICHOPHYTO 33.3% each o tonsurans, T. ru T. mentagroph	f T. brum,	(01)00365044528515 (17)201101 (10)T0000405 (21)00000020051
	1:10 W/V		
ltem: 5285ED Lot: T0000405 Exp: 2020Nov01	No U.S. Standard of Pote Dose/Route: 1 drop topic 5 mL Ite		NDC: 65044-5285-1 US License No. 1272
Non-Returnable	Store at 2-8°C RX Only Sterile Until Ope	ned	50000000649 - H01 50000000099 - H01

Trichophyton Mix, 5 mL 1:10 w/v Vial Label

ALL	ERGENIC	EXTRACT	NOH-
33.3% e	each of T. tonsu mentagrop	rans, T. rubrum, T. hytes	0000002619
5 mL Dose/Route:	1:10 W/V 1 drop topically	RX Only Sterile Until Opened Store at 2-8°C	HOI S
Preservative U.S. License	50% Glycerin v/v No. 1272	Item: 5285ED Lot: T0000405 Exp: 2020Nov01	000000143

FOOD - PLANT SOURCE, YEAST, BAKER SACCHAROMYCES CEREVISIAE

yeast, baker saccharomyces cerevisiae injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-3714
Route of Administration	PERCUTANEOUS		

Active Ingredient	Active Moiety		
	Ingredient Name	Basis of Streng	th Strength
YEAST (UNII: 3NY3SM	5B8U) (YEAST - UNII:3NY3SM6B8U)	YEAST	0.1 g in 1 mL
Inactive Ingredie	nts		
	Ingredient Name		Strength
GLYCERIN (UNII: PDC	6A3C0OX)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM BICARBONA	TE (UNII: 8MDF5V39QO)		
Packaging			
Packaging # Item Code	Package Description	Marketing Start Date	Marketing End Date
00	Package Description 5 mL in 1 VIAL; Type 0: Not a Combination Product	Marketing Start Date	Marketing End Date
# Item Code	J I	Marketing Start Date	Marketing End Date
# Item Code	5 mL in 1 VIAL; Type 0: Not a Combination Product	Marketing Start Date	Marketing End Date
 <i>Item Code</i> NDC:65044-3714-1 	5 mL in 1 VIAL; Type 0: Not a Combination Product	Marketing Start Date Marketing Start Date	Marketing End Date
 Item Code NDC:65044-3714-1 Marketing Inference 	5 mL in 1 VIAL; Type 0: Not a Combination Product		
 Item Code NDC:65044-3714-1 Marketing Info Marketing Category 	5 mL in 1 VIAL; Type 0: Not a Combination Product Ormation Application Number or Monograph Citation	Marketing Start Date	

yeast, brewer saccha	romyces cere	evisiae injection, solution		
Product Informati	ion			
Product Type		NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-3717
Route of Administrat	ion	PERCUTANEOUS		
Active Ingredient/	/Active Moi	ety		
	Ingred	ient Name	Basis of Strengt	th Strength
YEAST (UNII: 3NY3SM6	B8U) (YEAST -	UNII:3NY3SM6B8U)	YEAST	0.1 g in 1 mL
Inactive Ingredier	nts			
		Ingredient Name		Strength
GLYCERIN (UNII: PDC6	6A3C0OX)			
SODIUM CHLORIDE (U	UNII: 451W47IQ	3X)		
SODIUM BICARBONA	TE (UNII: 8 MDI	5V39QO)		
Packaging				

1 NDC:65044-3717-1	mL in 1 VIAL;	Type 0: Not a Combination Product					
Marketing Info	rmation						
Marketing Category	Applicatio	n Number or Monograph Citation	Μ	arketing	Start Date	Marketing	g End Date
BLA	BLA103888		04/	/19/1941			-
INSECTS WHO	LE BODY	Y COCKROACH MIX					
nsects whole body co	ckroach mix	injection, solution					
Product Informati	on						
Product T ype		NON-STANDARDIZED ALLERGENIC		Item Co	de (Source)	NDC:65	044-6585
Route of Administrati	on	PERCUTANEOUS					
Active Ingredient/	Active Moi	ety					
	In	gredient Name			Basis of S	Strength	Strength
PERIPLANETA AMERIC UNII:2RQ1L9N089)	C ANA (UNII: 2R	Q1L9N089) (PERIPLANETA AMERICAN	NA -		PERIPLANET AMERICANA		0.1 g in 1 mL
BLATTELLA GERMAN UNII:G9O67I0A8Q)	ICA (UNII: G9C	96710A8Q) (BLATTELLA GERMANICA	-		BLATTELLA GERMANICA		0.1 g in 1 mL
Inactive Ingredien	ts						
0		Ingredient Name				Stre	ngth
GLYCERIN (UNII: PDC6.	A3C0OX)	5					0
SODIUM CHLORIDE (U	NII: 451W47IQ8	3X)					
SODIUM BICARBONAT	E (UNII: 8 MDF	5V39QO)					
Packaging							
# Item Code	I	Package Description	Ma	rketing S	Start Date	Marketing	End Date
1 NDC:65044-6585-1	5 mL in 1 VIAL;	Type 0: Not a Combination Product					
Marketing Info	rmation						
Marketing Category		n Number or Monograph Citation	Μ	arketing	Start Date	Marketing	g End Date
BLA	BLA103888			/19/1941			, 2 att

INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS INVICTA

ant, fire solenopsis invicta injection, solution

Product Information

Product Type		NON-STANDARDIZED ALLERGENIC	Item Co	ode (Source)	NDC:	55044-6513
Route of Administrati	on	PERCUTANEOUS				
Active Ingredient//	Active Moie	ety				
0		gredient Name		Basis of S	trength	Strength
SOLENOPSIS INVICTA		- 4P444) (SOLENOPSIS INVICTA - UNII:5	507CR4P444)		-	0.1g in 1 mL
			,			U
Inactive Ingredien	its					
		Ingredient Name			Sti	rength
GLYCERIN (UNII: PDC6	A3C0OX)					
SODIUM CHLORIDE (U	NII: 451W47IQ8	3X)				
SODIUM BICARBONAT	T E (UNII: 8 MDF	5V39QO)				
Packaging						
# Item Code	I	Package Description	Marketing	Start Date	Marketin	ng End Date
1 NDC:65044-6513-1 5	5 mL in 1 VIAL;	Type 0: Not a Combination Product				
Maxbating Info	rmation					
warkeung mio						
Marketing Info	Applicatio	n Number or Monograph Citation	Marketing	g Start Date	Marketi	ng End Date
0	Applicatio BLA103888	n Number or Monograph Citation	Marketing 04/19/1941	g Start Date	Marketi	ng End Date

INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS RICHTERI

ant, fire solenopsis richteri injection, solution

Product Information					
Product T ype	NON-STANDARDIZED ALLERGENIC	Item Co	de (Source)	NDC:6	5044-6514
Route of Administration	PERCUTANEOUS				
Active Ingredient/Active Mo	iety				
I	ngredient Name		Basis of Stre	ength	Strength
SOLENOPSIS RICHTERI (UNII: 7396	84T11W) (SOLENOPSIS RICHTERI - UNII:7396	CO ATT 1 1 1 1 1	COLENODER D		
		50411100)	SOLENOPSIS R	ICHIERI	0.1g in 1 m
		56411100)	SULENUPSIS R	ICHIERI	0.1g in 1m
		56411100)	SOLENOPSIS R	ICHIERI	0.1g in 1m
Inactive Ingredients		504111w)	SOLENOPSIS R	ICHIERI	0.1g in 1m
	Ingredient Name	504111W)	SOLENOPSIS R		0.1g in 1 m ength
		504111W)	SOLENOPSIS R		-
Inactive Ingredients	Ingredient Name	55411100)	SULENUPSIS R		-

1 4	ckaging					
#	Item Code	l	Package Description	Marketing S	Start Date	Marketing End Date
1 N	DC:65044-6514-1	5 mL in 1 VIAL;	Type 0: Not a Combination Product			
Ma	arketing Info	ormation				
Ma	rketing Category	Applicatio	on Number or Monograph Citation	Marketing	Start Date	Marketing End Date
BLA	L	BLA103888		04/19/1941		06/29/2018
	SECTS WHO		Y, FIRE ANT MIX			
Pre	oduct Informat	ion				
Pro	duct T ype		NON-STANDARDIZED ALLERGENIC	Item Co	de (Source)	NDC:65044-6515
Rou	ite of Administra	tion	PERCUTANEOUS			
Act	tive Ingredient	Active Moi	ety			
Act	tive Ingredient		ety gredient Name		Basis of S	Strength Strengtl
SOI	LENOPSIS RICHTE	In E RI (UNII: 73968	gredient Name 44T11W) (SOLENOPSIS RICHTERI - UNI		SOLENOPS	IS RICHTERI 0.1 g in 1 m
SOI	LENOPSIS RICHTE	In E RI (UNII: 73968	gredient Name		SOLENOPS	IS RICHTERI 0.1 g in 1 m
501 501	LENO PSIS RICHTE	In ERI (UNII: 73968 A (UNII: 507CR4	gredient Name 44T11W) (SOLENOPSIS RICHTERI - UNI		SOLENOPS	IS RICHTERI 0.1 g in 1 m
501 501	LENOPSIS RICHTE	In ERI (UNII: 73968 A (UNII: 507CR4	gredient Name 94T11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5		SOLENOPS	IS RICHTERI 0.1g in 1m IS INVICTA 0.1g in 1m
soi soi Ina	LENOPSIS RICHTE LENOPSIS INVICT.	In ERI (UNII: 73968 A (UNII: 507CR4 nts	gredient Name 44T11W) (SOLENOPSIS RICHTERI - UNI		SOLENOPS	IS RICHTERI 0.1 g in 1 m
soi soi Ina GLY	LENO PSIS RICHTE	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX)	gredient Name 44T11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name		SOLENOPS	IS RICHTERI 0.1g in 1m IS INVICTA 0.1g in 1m
SOI SOI Ina GLY SOI	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredie YCERIN (UNII: PDC)	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ8	gredient Name 94T11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8X)		SOLENOPS	IS RICHTERI 0.1g in 1m IS INVICTA 0.1g in 1m
SOI SOI Ina GLY SOI	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredie YCERIN (UNII: PDC) DIUM CHLORIDE (In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ8	gredient Name 94T11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8X)		SOLENOPS	IS RICHTERI 0.1g in 1m IS INVICTA 0.1g in 1m
SOI SOI Ina GLN SOI SOI	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredie YCERIN (UNII: PDC) DIUM CHLORIDE (In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ8	gredient Name 94T11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8X)		SOLENOPS	IS RICHTERI 0.1g in 1m IS INVICTA 0.1g in 1m
SOI SOI Ina GLN SOI SOI Pac	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredie VCERIN (UNII: PDC) DIUM CHLO RIDE (DIUM BICARBO NA	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ4 TE (UNII: 8 MDF	gredient Name 94T11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8X)		SOLENOPS	IS RICHTERI 0.1 g in 1 m IS INVICTA 0.1 g in 1 m Strength
SOI SOI Ina GLY SOI SOI Pac #	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredies YCERIN (UNII: PDC) DIUM CHLO RIDE (DIUM BICARBO NA	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ4 TE (UNII: 8 MDF	gredient Name gat111W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8X) 75V39QO)	O7CR4P444)	SOLENOPS	IS RICHTERI 0.1 g in 1 m IS INVICTA 0.1 g in 1 m
SOI SOI Ina GLY SOI SOI Pac #	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredies YCERIN (UNII: PDC) DIUM CHLO RIDE (DIUM BICARBO NA	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ4 TE (UNII: 8 MDF	gredient Name gatT11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8 X) 75V39QO) Package Description	O7CR4P444)	SOLENOPS	IS RICHTERI 0.1 g in 1 n IS INVICTA 0.1 g in 1 n Strength
SOI SOI GLY SOI SOI H 1 N	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredies YCERIN (UNII: PDC) DIUM CHLO RIDE (DIUM BICARBO NA	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ4 TE (UNII: 8 MDF 1 5 mL in 1 VIAL;	gredient Name gatT11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8 X) 75V39QO) Package Description	O7CR4P444)	SOLENOPS	IS RICHTERI 0.1 g in 1 m IS INVICTA 0.1 g in 1 m Strength
SOI SOI Ina GLY SOI SOI Pac # 1 N	LENO PSIS RICHTE LENO PSIS INVICT. Active Ingredies VCERIN (UNII: PDC) DIUM CHLO RIDE (DIUM BICARBO NA Ckaging Item Code DC:65044-6515-1	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ4 TE (UNII: 8 MDF 5 mL in 1 VIAL; Drmation	gredient Name gatT11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8 X) 75V39QO) Package Description	O7CR4P444)	SOLENOPS SOLENOPS Solenops Start Date	IS RICHTERI 0.1 g in 1 m IS INVICTA 0.1 g in 1 m Strength
SOI SOI Ina GLY SOI SOI Pac # 1 N	LENOPSIS RICHTE LENOPSIS INVICT. Active Ingredien CCERIN (UNII: PDC) DIUM CHLORIDE (DIUM BICARBONA Ckaging Item Code DC:65044-6515-1	In ERI (UNII: 73968 A (UNII: 507CR4 nts 6 A3C0OX) UNII: 451W47IQ4 TE (UNII: 8 MDF 5 mL in 1 VIAL; Drmation	gredient Name gatT11W) (SOLENOPSIS RICHTERI - UNI 4P444) (SOLENOPSIS INVICTA - UNII:5 Ingredient Name 8X) 75V39QO) Package Description Type 0: Not a Combination Product	O7CR4P444) Marketing S	SOLENOPS SOLENOPS Solenops Start Date	IS RICHTERI 0.1 g in 1 r IS INVICTA 0.1 g in 1 r Strength Marketing End Dat

MOLDS - ALTERNARIA/HORMODENDRUM MIX

molds - alternaria/hormodendrum mix injection, solution

Product Informat	ion					
Product Type		NON-STANDARDIZED ALLERGENIC	Ite m (Code (Source)	NDC:650	44-5003
Route of Administrat	tion	PERCUTANEOUS				
Active Ingredient	Active Moi	ety				
	Ing	redient Name		Basis of S	Strength	Strength
ALTERNARIA ALTERI UNII:52B29REC7H)	NATA (UNII: 521	329 REC7H) (ALTERNARIA ALTERNATA	1 -	ALTERNARIA	ALTERNATA	0.1 g in 1 mL
CLADOSPORIUM CLA CLADOSPORIOIDES - U		ES (UNII: 4ZWY20GTGO) (CLADOSPOF GO)	RIUM	CLADOSPORIO CLADOSPORIO		0.1 g in 1 mL
Inactive Ingredie	nts					
		Ingredient Name			Strei	ngth
GLYCERIN (UNII: PDC)	6A3C0OX)					
SODIUM CHLORIDE (UNII: 451W47IQ8	3X)				
SODIUM BICARBONA	TE (UNII: 8 MDF	5V39QO)				
Packaging						
# Item Code]	Package Description	Marketin	g Start Date	Marketing	End Date
1 NDC:65044-5003-1	5 mL in 1 VIAL;	Type 0: Not a Combination Product				
Marketing Info	ormation					
Marketing Category	Applicatio	on Number or Monograph Citation	Marketi	ng Start Date	Marketing	End Date
BLA	BLA103888		04/19/1942	1		

MOLDS - MOLD MIX 10

molds - mold mix 10 injection, solution

Product Information						
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-5137			
Route of Administration	PERCUTANEOUS					

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ALTERNARIA ALTERNATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA - UNII:52B29REC7H)	ALTERNARIA ALTERNATA	0.1 g in 1 mL			
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)	ASPERGILLUS FUMIGATUS	0.025 g in 1 mL			
ASPERGILLUS NIDULANS (UNII: 242A53RB80) (ASPERGILLUS NIDULANS - UNII:242A53RB80)	ASPERGILLUS NIDULANS	0.025 g in 1 mL			
ASPERGILLUS NIGER VAR. NIGER (UNII: 910A40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:910A40ANG6)	ASPERGILLUS NIGER VAR. NIGER	0.025 g in 1 mL			

UNII:QBN8K7055X) FUSARIUM O XYSPORU	US (UNII: QBN8K7055X) (ASPERGILLUS TERREUS -			
OXYSPORUM VASINFEC		ASPERGILLUS T	ERREUS	0.025 g in 1 mL
DENDRYPHIELLA VINC	U M VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM CTUM - UNII:6M98DC08TZ)	FUSARIUM O XYS VASINFECTUM	SPORUM	0.1 g in 1 mL
UNII:7S6NW5FH8X)	A VINOSA	0.1 g in 1 mL		
CLADOSPORIUM CLAI CLADOSPORIOIDES - U	1 DES	0.1 g in 1 mL		
MUCOR RACEMOSUS (UNII:17RH99LQ7G)	DSUS	0.1 g in 1 mL		
PENICILLIUM DIGITAT UNII:1SB49SV239)	T UM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM -	PENICILLIUM DIG	GITATUM	0.02 g in 1 mL
PENICILLIUM EXPANS UNII:1XSC3BB35Z)	UM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM -	PENICILLIUM EX	PANSUM	0.04 g in 1 mL
	GENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) GENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CH VAR. CHRYSOGE		0.02 g in 1 mL
CLONOSTACHYS ROS F. ROSEA - UNII:15F729V	EA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS RO VZ2H)	SEA CLONOSTACHY ROSEA	S ROSEA F.	0.02 g in 1 mL
PHO MA EXIGUA VAR. I UNII:8 JAG41IE4M)	VAR. EXIGUA	0.1 g in 1 mL		
AUREO BASIDIUM PULI (AUREO BASIDIUM PULI	M R.	0.1 g in 1 mL		
RHIZOPUS STOLONIF	ONIEED	0.1 g		
UNII:FEE198DK4Q)		RHIZOPUS STOL	ONIFER	in 1 mL
	ts			
UNII:FEE198DK4Q)	ts Ingredient Name		Stren	
UNII:FEE198DK4Q)	Ingredient Name			
UNII:FEE198DK4Q) Inactive Ingredien	Ingredient Name A3C0OX)			
UNII:FEE198DK4Q) Inactive Ingredien GLYCERIN (UNII: PDC6	Ingredient Name A3C0OX) INII: 451W47IQ8X)			
UNII:FEE198DK4Q) Inactive Ingredien GLYCERIN (UNII: PDC6 SODIUM CHLORIDE (U SODIUM BICARBONAT	Ingredient Name A3C0OX) INII: 451W47IQ8X)			
UNII: FEE 198 DK4Q) Inactive Ingredien GLYCERIN (UNII: PDC6 SO DIUM CHLO RIDE (U SO DIUM BICARBO NAT	Ingredient Name A3C0OX) INII: 451W47IQ8X)		Stren	gth
UNII:FEE198DK4Q) Inactive Ingredien GLYCERIN (UNII: PDC6 SODIUM CHLORIDE (U SODIUM BICARBONAT	Ingredient Name A3C0OX) INII: 451W47IQ8X) FE (UNII: 8MDF5V39QO)	arketing Start Date		gth
UNII:FEE198DK4Q) INICIPAL STATES STAT	Ingredient Name A3C0OX) INII: 451W47IQ8X) FE (UNII: 8MDF5V39QO)		Stren	gth
UNII:FEE198DK4Q) Inactive Ingredien GLYCERIN (UNII: PDC6 SO DIUM CHLORIDE (U SO DIUM BICARBONAT Packaging # Item Code	Ingredient Name A3C0OX) INII: 451W47IQ8X) FE (UNII: 8MDF5V39QO) Package Description		Stren	gth
UNII:FEE198DK4Q) Inactive Ingredien GLYCERIN (UNII: PDC6 SO DIUM CHLORIDE (U SO DIUM BICARBONAT Packaging # Item Code	Ingredient Name A3C0OX) INII: 451W47IQ8X) FE (UNII: 8MDF5V39QO) FE (UNII: 8MDF5V39QO) Package Description Main Som L in 1 VIAL; Type 0: Not a Combination Product		Stren	gth
UNII:FEE 198 DK4Q)	Ingredient Name A3C0OX) INII: 451W47IQ8X) TE (UNII: 8 MDF5V39QO) Package Description Mage Description 5 mL in 1 VIAL; Type 0: Not a Combination Product rmation		Stren	gth End Date

MOLDS - MOLD MIX 4 molds - mold mix 4 injection, solution Product Information Product Type NON-STANDARDIZED ALLERGENIC Route of Administration PERCUTANEOUS

Active Ingredient	/Active Moiety				
	Ingredient Name		Basis of St	rength	Strength
ALTERNARIA ALTER UNII:52B29REC7H)	NATA (UNII: 52B29REC7H) (ALTERNARIA ALTERNATA	ł -	ALTERNARIA AL	TERNATA	0.1 g in 1 mL
ASPERGILLUS FUMIC UNII:X88DF51T48)	GATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATU	8) (ASPERGILLUS FUMIGATUS - ASPERGILLUS F			0.025 g in 1 mL
ASPERGILLUS NIDUL UNII:242A53RB80)	LANS (UNII: 242A53RB80) (ASPERGILLUS NIDULANS - ASPERGILLUS N				0.025 g in 1 mL
ASPERGILLUS NIGER NIGER - UNII:910A40A	LLUS NIGER VAR. NIGER (UNII: 9 IOA40 ANG6) (ASPERGILLUS NIGER VAR. ASPERGILLUS NI NII: 9 IOA40 ANG6) ASPERGILLUS NIGER VAR. ASPERGILLUS NI				
ASPERGILLUS TERRI UNII:QBN8K7055X)	EUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS -		ASPERGILLUS TE	ERREUS	0.025 g in 1 mL
CLADOSPORIUM CLA CLADOSPORIOIDES -	ADO SPORIOIDES (UNII: 4ZWY20GTGO) (CLADO SPOR UNII:4ZWY20GTGO)	RIUM	CLADOSPORIUM CLADOSPORIOIE		0.1 g in 1 mL
PENICILLIUM DIGITA UNII:1SB49SV239)	TUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM -		PENICILLIUM DIG	ITATUM	0.025 g in 1 mL
PENICILLIUM EXPAN UNII:1XSC3BB35Z)	SUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM -		PENICILLIUM EXI	PANSUM	0.05 g in 1 mL
	OGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) OGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)		PENICILLIUM CHI VAR. CHRYSOGE		0.025 g in 1 mL
CLONOSTACHYS RO F. ROSEA - UNII:15F729	SEA F. ROSEA (UNII: I5F729 WZ2H) (CLONOSTACHYS WZ2H)	ROSEA	CLONOSTACHYS ROSEA	S ROSEA F.	0.025 g in 1 mL
Inactive Ingredie	nts				
	Ingredient Name			Stren	ıgth
GLYCERIN (UNII: PDC					
SODIUM CHLORIDE (- /				
SO DIUM BICARBONA	TE (UNII: 8 MDF5V39QO)				
Packaging					
# Item Code	Package Description	Marketi	ng Start Date	Marketing	End Date
1 NDC:65044-5002-1	5 mL in 1 VIAL; Type 0: Not a Combination Product				
Marketing Info	ormation				
Marketing Category		Marke	ting Start Date	Marketing	End Date
BLA	BLA103888	04/19/19	-		

MOLDS - TRICHOPHYTON MIX molds - trichophyton mix injection, solution Product Information Product Type NON-STANDARDIZED ALLERGENIC Route of Administration PERCUTANEOUS

UNII:JY1BE3		Ingredient Name	Basis of S	Strength	Strengt	
		NSURANS (UNII: JY1BE33I3Y) (TRICHOPHYTON TONSU	TRICHOPHYTON TONSURANS		0.1 g in 1 mL	
TRICHOPHYTON RUBRUM (UNII: 2ZAU32517N) (TRICHOPHYTON RUBRUM - UNII:2ZAU32517N)				TRICHOPHYTON RUBRUM		0.1 g in 1 mL
		TAGROPHYTES (UNII: 19917J3JIV) (TRICHOPHYTON 'NII:19917J3JIV)		TRICHOPHYTON MENTAGROPHYTES		0.1 g in 1 mL
Inactive I	Ingredie	ıts				
	U	Ingredient Name			Stre	ngth
GLYCERIN	(UNII: PDC	SA3C0OX)				
SODIUM CI	HLORIDE (UNII: 451W47IQ8X)				
SO DIUM BI	ICARBO NA	TE (UNII: 8MDF5V39QO)				
Packagin	ıg					
# Item	Code	Package Description	Marketi	ng Start Date	Marketing	End Date
	44-5285-1	5 mL in 1 VIAL; Type 0: Not a Combination Product				
1 NDC:6504						
	ing Info	ormation				
Market	0	ormation	Market	ing Start Date	Marketing	End Date
	0		Market 04/19/194	ing Start Date	Marketing	; End Date

MOLDS, PENICILLIUM MIX

molds, penicillium mix injection, solution

Product Information						
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-5169			
Route of Administration	PERCUTANEOUS					

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239)	PENICILLIUM DIGITATUM	0.1 g in 1 mL				
PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z)	PENICILLIUM EXPANSUM	0.2 g in 1 mL				
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	0.1 g in 1 mL				
CLONOSTACHYS ROSEA F. ROSEA (UNII: 15F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:15F729WZ2H)	CLONOSTACHYS ROSEA F. ROSEA	0.1 g in 1 mL				

		Ingredient Name			Str	ength
GLYCERIN (UNII: PDC6	GA3C0OX)					
SODIUM CHLORIDE (U	UNII: 451W47IQ8	3X)				
SODIUM BICARBONA	TE (UNII: 8 MDF	5V39QO)				
Packaging						
# Item Code	l	Package Description	Marketing	Start Date	Marketin	g End Date
1 NDC:65044-5169-1	5 mL in 1 VIAL;	Type 0: Not a Combination Product				
Marketing Info	rmation					
Marketing Category	Applicatio	on Number or Monograph Citation	Marketin	g Start Date	Marketir	ig End Date
BLA	BLA103888		04/19/1941			
		IUTS, ALTERNARIA TI	ENUIS			
ilternaria tenuis injec	tion, solution					
Product Informati	ion					
Product T ype		NON-STANDARDIZED ALLERGENIC	Item C	ode (Source)	NDC:6	5044-5009
			ite in c	oue (Source)		
Route of Administrat	ion	PERCUTANEOUS				
	Active Moi	ety				
Active Ingredient/	Active Moio/ Ing	ety gredient Name		Basis of S	Strength	-
Active Ingredient/	Active Moio/ Ing	ety			Strength A	Strength 0.1 g in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H)	/Active Moi In NATA (UNII: 521	ety gredient Name		Basis of S	Strength A	0.1 g
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H)	/Active Moi In NATA (UNII: 521	ety gredient Name		Basis of S	Strength A	0.1 g
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6	/Active Moi Ing NATA (UNII: 521 NATA (JNII: 521	ety gredient Name 329 REC7H) (ALTERNARIA ALTERNATA Ingredient Name		Basis of S	Strength A	0.1 g in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6 SODIUM CHLORIDE (U	/Active Moi In NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 451W47IQ8	ety gredient Name 329 REC7H) (ALTERNARIA ALTERNATA Ingredient Name 3X)		Basis of S	Strength A	0.1 g in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6 SODIUM CHLORIDE (U	/Active Moi In NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 451W47IQ8	ety gredient Name 329 REC7H) (ALTERNARIA ALTERNATA Ingredient Name 3X)		Basis of S	Strength A	0.1 g in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6 SODIUM CHLORIDE (U SODIUM BICARBONA	/Active Moi In NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 521 NATA (UNII: 451W47IQ8	ety gredient Name 329 REC7H) (ALTERNARIA ALTERNATA Ingredient Name 3X)		Basis of S	Strength A	0.1 g in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29 REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6 SO DIUM CHLO RIDE (I SO DIUM BICARBO NA Packaging # Item Code	/Active Moi Ing NATA (UNII: 521 NATA (UNII: 521 NII: 451W471Q TE (UNII: 8MDF	ety gredient Name 329REC7H) (ALTERNARIA ALTERNATA Ingredient Name 3X) 5V39QO) Package Description	A -	Basis of S	Strength A Str	in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29 REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6 SO DIUM CHLORIDE (U SO DIUM BICARBONA Packaging # Item Code	/Active Moi Ing NATA (UNII: 521 NATA (UNII: 521 NII: 451W471Q TE (UNII: 8MDF	ety gredient Name 329 REC7H) (ALTERNARIA ALTERNATA Ingredient Name 3X) 5V39QO)	A -	Basis of S ALTERNARI ALTERNATA	Strength A Str	0.1g in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6 SODIUM CHLORIDE (U SODIUM BICARBONA Packaging # Item Code	/Active Moid Ing NATA (UNII: 521 NATA (UNII: 521 NII: 451 JUNII: 451W47IQ8 TE (UNII: 8 MDF ITE (UNII: 8 MDF	ety gredient Name 329REC7H) (ALTERNARIA ALTERNATA Ingredient Name 3X) 5V39QO) Package Description	A -	Basis of S ALTERNARI ALTERNATA	Strength A Str	0.1g in 1 mL
Active Ingredient/ ALTERNARIA ALTERN UNII:52B29REC7H) Inactive Ingredien GLYCERIN (UNII: PDC6 SO DIUM CHLORIDE (U SO DIUM BICARBONA Packaging # Item Code 1 NDC:65044-5009-1	Active Moie Ing NATA (UNII: 52H NATA (UNII: 52H NII: 451W47IQ8 TE (UNII: 8MDF 5 mL in 1 VIAL; 9rmation	ety gredient Name 329REC7H) (ALTERNARIA ALTERNATA Ingredient Name 3X) 5V39QO) Package Description	A - Marketing	Basis of S ALTERNARI ALTERNATA	Strength A Str Marketin	0.1g in 1 mL

Product Informat	ion				
Product T ype	NON-STANDARDIZED ALLERGENIC	Ite m C	Code (Source)	NDC:6	5044-5021
Route of Administrat	tion PERCUTANEOUS				
Active Ingredient	/Active Moiety				
	Ingredient Name		Basis of S	Strength	Strengt
ASPERGILLUS FUMIG UNII:X88DF51T48)	ATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATU	JS -	ASPERGILLU FUMIGATUS	JS	0.1 g in 1 mL
Inactive Ingredie	nts				
	Ingredient Name			Str	ength
GLYCERIN (UNII: PDC)	5A3C0OX)				
SODIUM CHLORIDE (
SODIUM BICARBONA	TE (UNII: 8MDF5V39QO)				
Packaging					
# Item Code	Package Description	Marketing	g Start Date	Marketin	g End Dat
NDC:65044-5021-1	5 mL in 1 VIAL; Type 0: Not a Combination Product				
Marketing Info	ormation				
Marketing Category	Application Number or Monograph Citation	Marketin	ng Start Date	Marketin	g End Dat
BLA	BLA103888	04/19/1941			

Product Information							
Product Type	NON-STANDARDIZED ALLERGENIC	Ite m Co	de (Source)	NDC:650	44-5033		
Route of Administration	PERCUTANEOUS						
Active Ingredient/Active Moiety							
Ing	gredient Name		Basis of Stre	ngth	Strength		
ASPERGILLUS NIGER VAR. NIGER (NIGER - UNII: 910 A40 ANG6)	UNII: 910A40ANG6) (ASPERGILLUS NIGER V	/AR.	ASPERGILLUS NIC	GER VAR.	0.1 g in 1 mL		

Inactive Ingredients						
	Strength					
GLYCERIN (UNII: PDC6A3C0OX)						
SODIUM CHLORIDE (U	JNII: 451W47IQ8X)					
SODIUM BICARBONA	TE (UNII: 8MDF5V39QO)					
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:65044-5033-1	5 mL in 1 VIAL; Type 0: Not a Combination Product					
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
BLA	BLA103888	04/19/1941				

MOLDS, RUSTS	S AND SM	IUTS, BOTRYTIS CINE	RE.	A			
botrytis cinerea injecti	ion, solution						
Product Information	on						
Product Type		NON-STANDARDIZED ALLERGENIC		Ite m Co	de (Source)	NDC:	65044-5049
Route of Administrati	on	PERCUTANEOUS					
Active Ingredient/	Active Moi	ety					
	In	gredient Name			Basis of S	trength	Strength
BOTRYTIS CINEREA (U	UNII: TBW53313	887) (BOTRYTIS CINEREA - UNII:TBW5	33135	57)	BOTRYTIS C	CINEREA	0.1g in 1mL
Inactive Ingredien	te						
macuve mgreuten		Ingredient Name				St	rength
GLYCERIN (UNII: PDC6.	A3C0OX)	Ingreatent Name				51	iringtii
SODIUM CHLORIDE (U		3X)					
SODIUM BICARBONAT	Г Е (UNII: 8 MDF	5V39QO)					
Packaging							
# Item Code	I	Package Description	Ma	rketing S	Start Date	Marketi	ng End Date
1 NDC:65044-5049-1	5 mL in 1 VIAL;	Type 0: Not a Combination Product					
Marketing Info	rmation						
Marketing Category	Applicatio	n Number or Monograph Citation	Μ	arketing	Start Date	Market	ing End Date

04/19/1941

Labeler - Jubilant HollisterStier LLC (069263643)

Registrant - Jubilant HollisterStier LLC (069263643)

Revised: 1/2020

Jubilant HollisterStier LLC