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 HollisterStier 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. AP™ (acetone precipitated) extracts, if present, are prepared by reconstituting dry, allergenically active concentrates produced by precipitation process from extracts of raw materials. For those AP™ 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 1[12], Amb a 2[13], Ra3[14], Ra4(BPA-R)[15], Ra5[16], Ra6, Ra7, and Ra8[17], and cytochrome C[18]), 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 anti-serum 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 $ID_{50}EAL$ 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 epinephrine-hydrochloride 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 ± Std. Dev. (mm)	Mean Sum of Erythema ± 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 ∑E (sum of the longest diameter and the mid-point orthogonal diameters of erythema) is also presented.

Grade	Erythema mm	Papule or Wheal mm	Corresponding 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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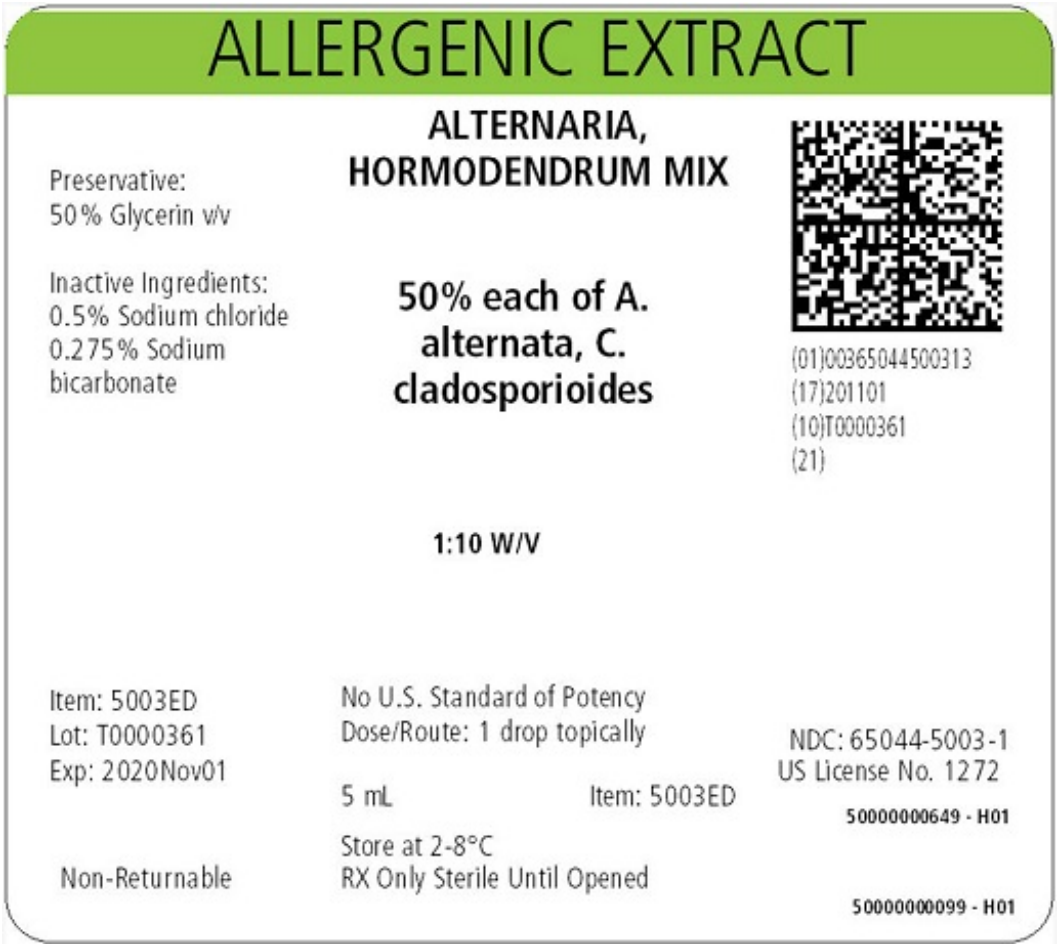
Cockroach Mix, 5 mL 1:10 w/v Carton Label

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

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

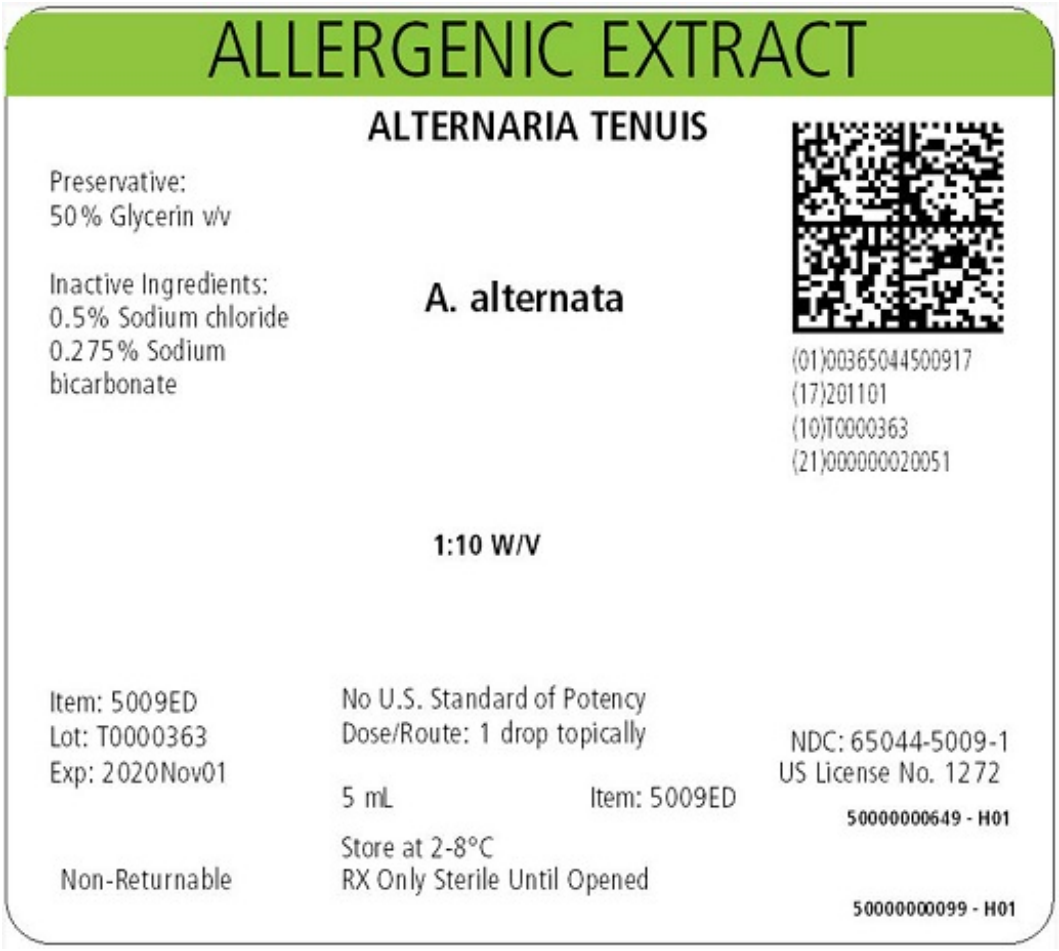
Fire Ant Mix, 5 mL 1:10 w/v Vial Label

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

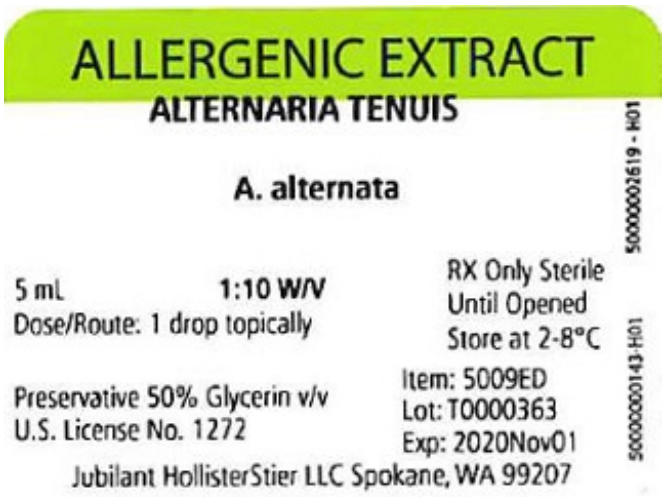


Alternaria Hormodendrum Mix, 5 mL 1:10 w/v Vial Label

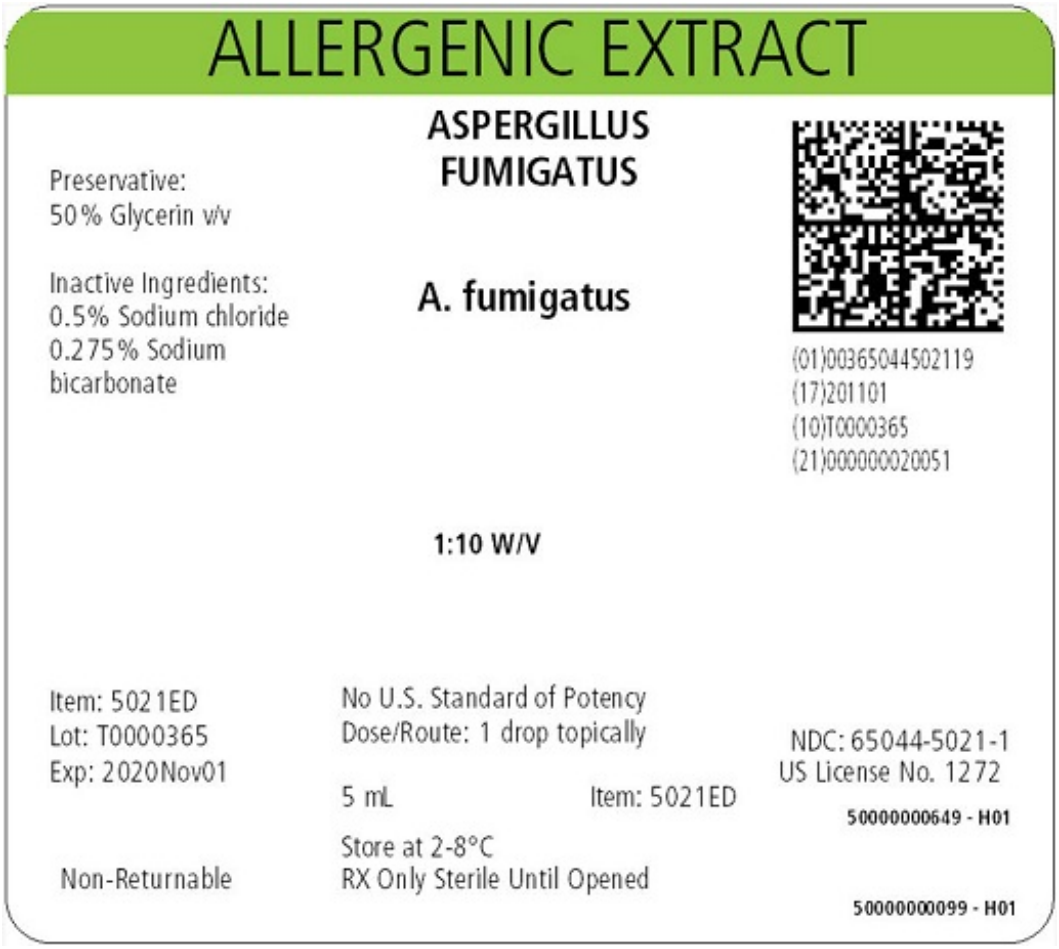
Alternaria *tenuis*, 5 mL 1:10 w/v Carton Label



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



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

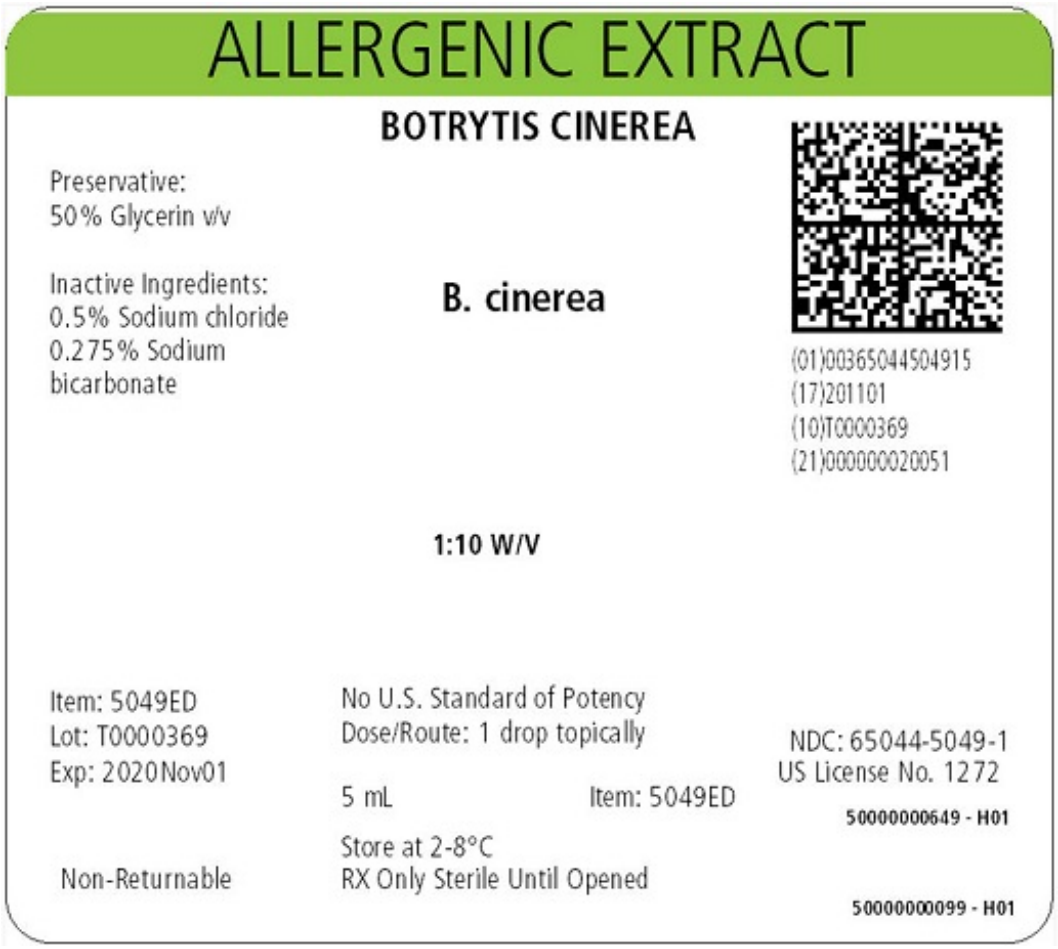


Aspergillus *fumigatus*, 5 mL 1:10 w/v Vial Label

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

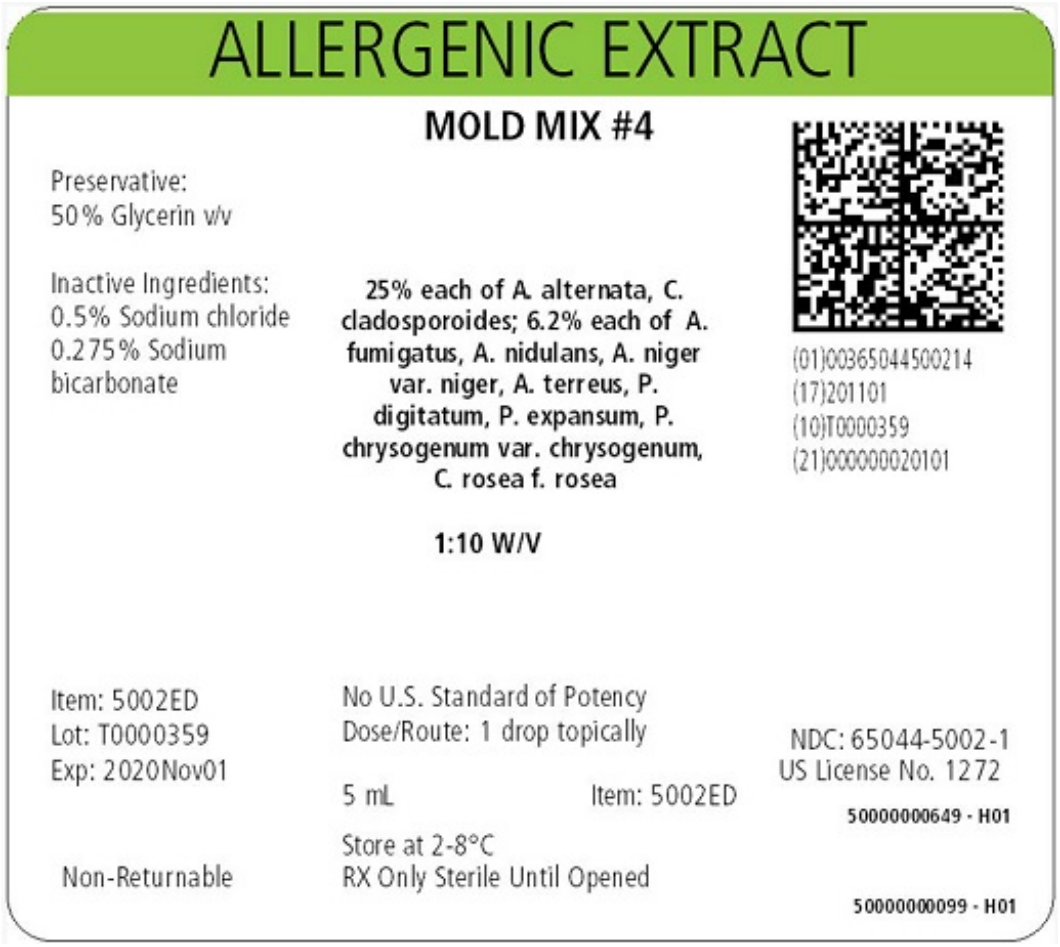
Aspergillus *niger*, 5 mL 1:10 w/v Vial Label

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



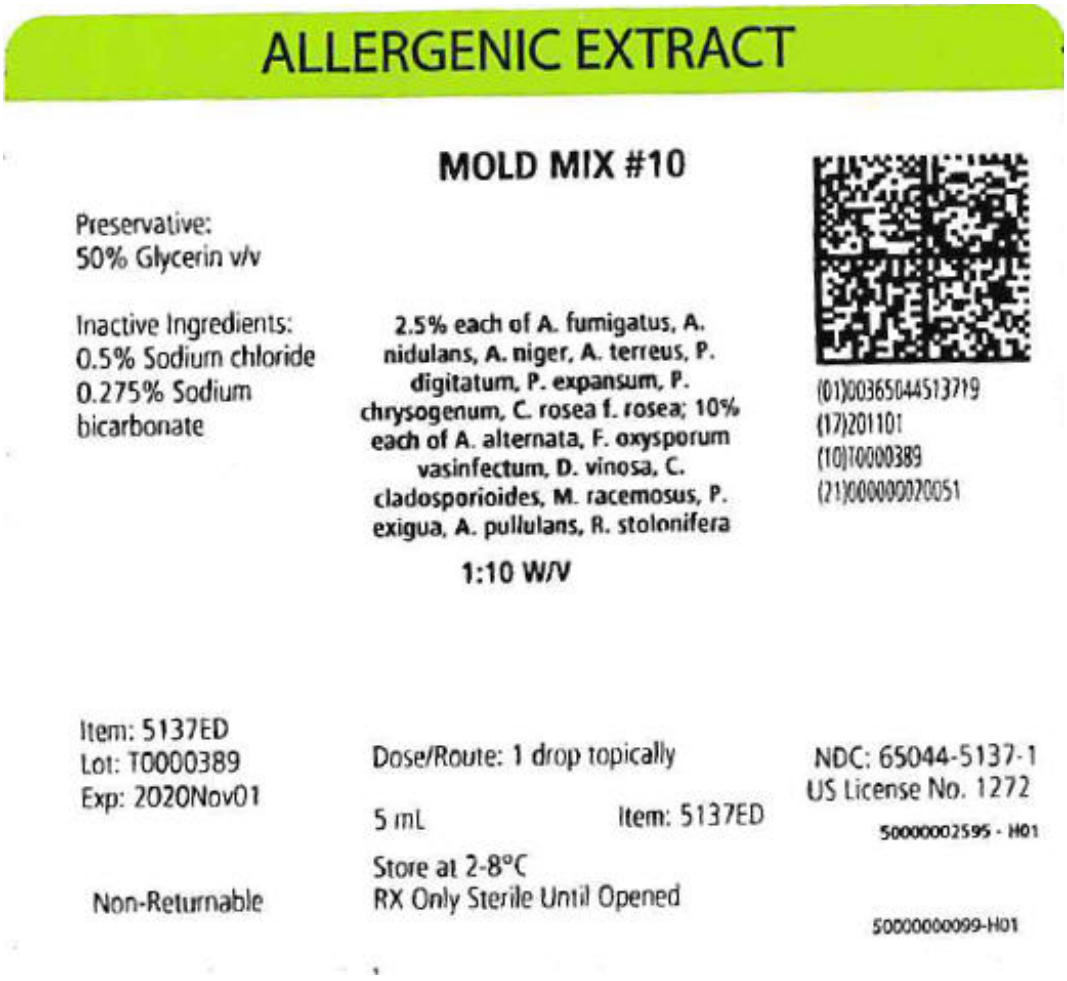
Botrytis *cinerea*, 5 mL 1:10 w/v Vial Label

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



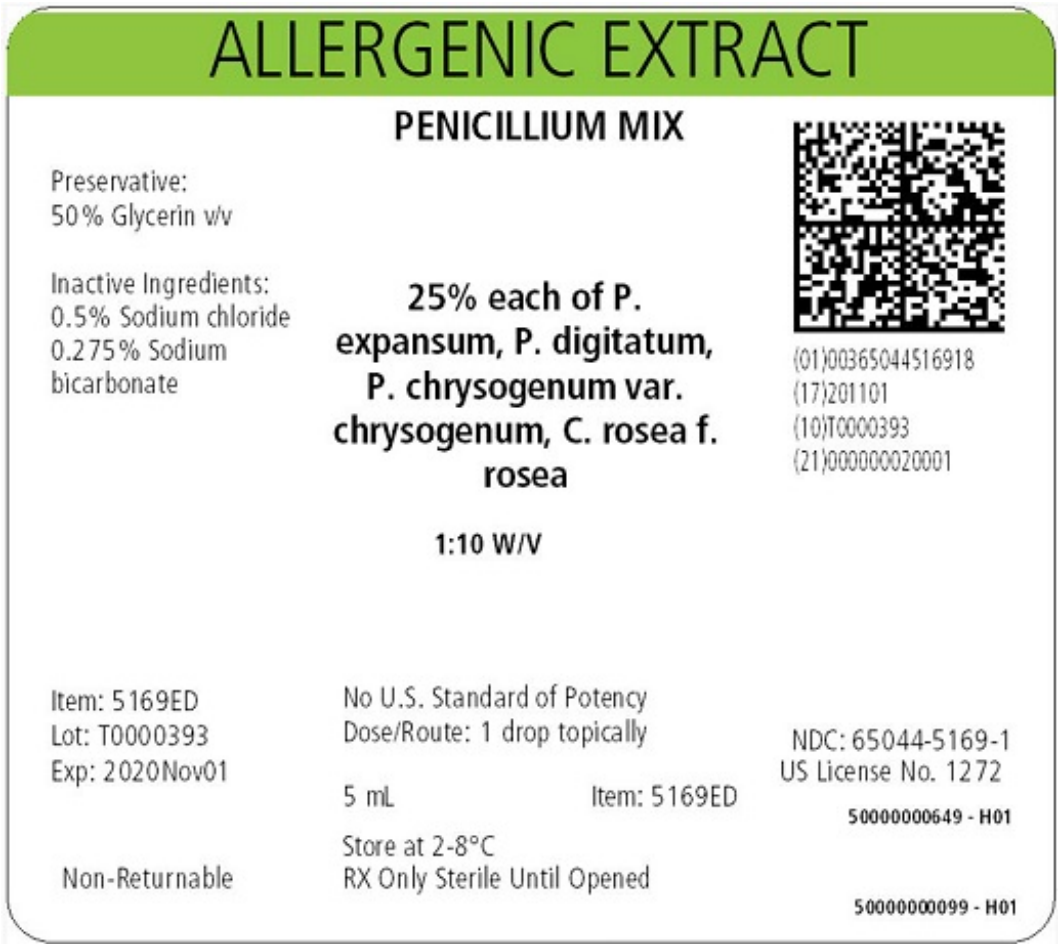
Mold Mix #4, 5 mL 1:10 w/v Vial Label

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

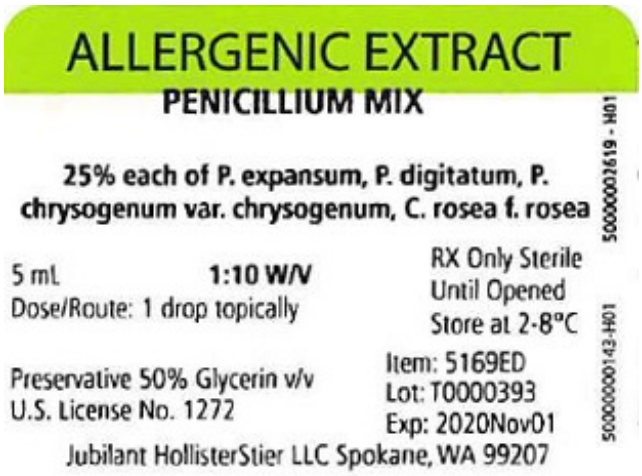


Mold Mix #10, 5 mL 1:10 w/v Vial Label

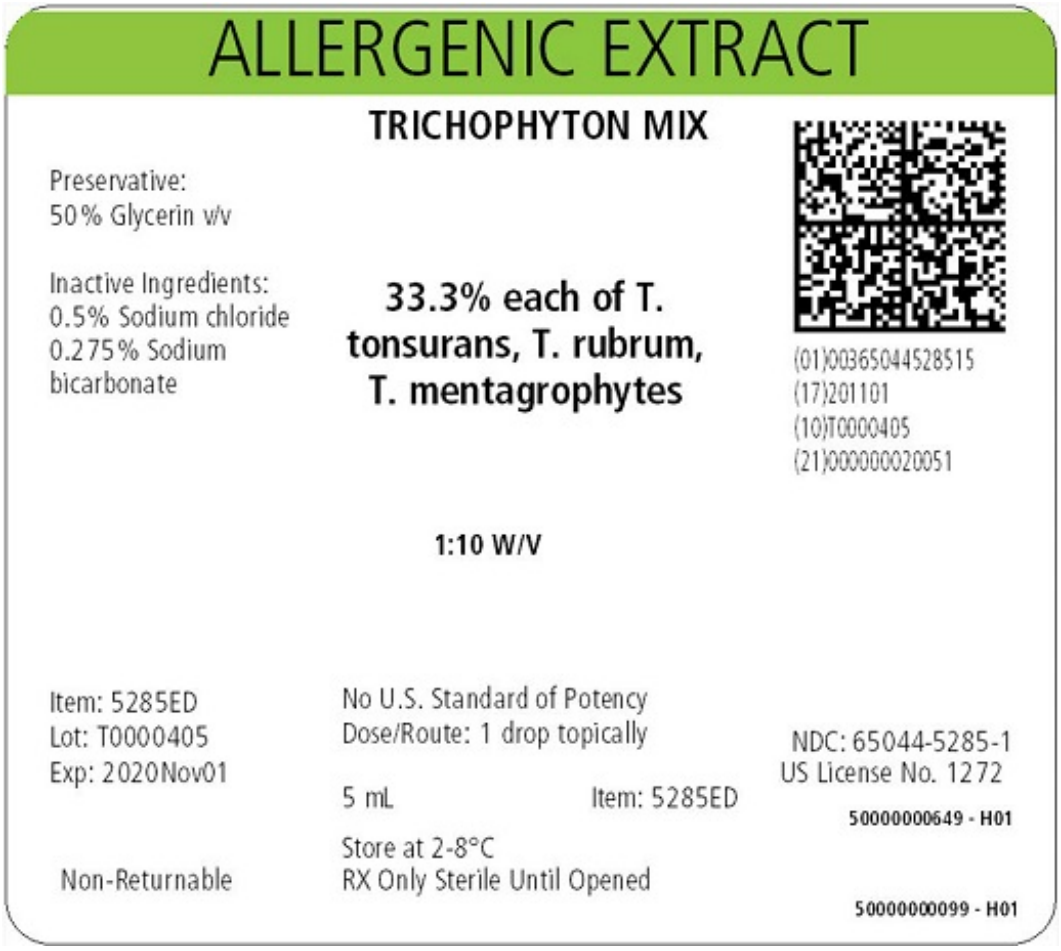
Penicillium Mix, 5 mL 1:10 w/v Carton Label



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



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



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

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 Strength**	**Strength**
YEAST (UNII: 3NY3SM6B8U) (YEAST - UNII:3NY3SM6B8U)	YEAST	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65044-3714-1	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	

FOOD - PLANT SOURCE, YEAST, BREWER SACCHAROMYCES CEREVISIAE

yeast, brewer saccharomyces cerevisiae injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-3717
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
YEAST (UNII: 3NY3SM6B8U) (YEAST - UNII:3NY3SM6B8U)	YEAST	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:65044-3717-1	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	

INSECTS WHOLE BODY COCKROACH MIX

insects whole body cockroach mix injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-6585
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089)	PERIPLANETA AMERICANA	0.1 g in 1 mL
BLATTELLA GERMANICA (UNII: G9O67I0A8Q) (BLATTELLA GERMANICA - UNII:G9O67I0A8Q)	BLATTELLA GERMANICA	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-6585-1	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	

INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS INVICTA

ant, fire solenopsis invicta injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-6513
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SOLENOPSIS INVICTA (UNII: 5O7CR4P444) (SOLENOPSIS INVICTA - UNII:5O7CR4P444)	SOLENOPSIS INVICTA	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-6513-1	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	

INSECTS WHOLE BODY, ANT, FIRE SOLENOPSIS RICHTERI

ant, fire solenopsis richteri injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-6514
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SOLENOPSIS RICHTERI (UNII: 739684T11W) (SOLENOPSIS RICHTERI - UNII:739684T11W)	SOLENOPSIS RICHTERI	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-6514-1	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	06/29/2018

INSECTS WHOLE BODY, FIRE ANT MIX

insects whole body, fire ant mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-6515
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SOLENOPSIS RICHTERI (UNII: 739684T11W) (SOLENOPSIS RICHTERI - UNII:739684T11W)	SOLENOPSIS RICHTERI	0.1 g in 1 mL
SOLENOPSIS INVICTA (UNII: 5O7CR4P444) (SOLENOPSIS INVICTA - UNII:5O7CR4P444)	SOLENOPSIS INVICTA	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-6515-1	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 - ALTERNARIA/HORMODENDRUM MIX

molds - alternaria/hormodendrum mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-5003
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
CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)	CLADOSPORIUM CLADOSPORIOIDES	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65044-5003-1	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 - 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: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6)	ASPERGILLUS NIGER VAR. NIGER	0.025 g in 1 mL

ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X)	ASPERGILLUS TERREUS	0.025 g in 1 mL
FUSARIUM OXYSPORUM VASINFECTUM (UNII: 6M98DC08TZ) (FUSARIUM OXYSPORUM VASINFECTUM - UNII:6M98DC08TZ)	FUSARIUM OXYSPORUM VASINFECTUM	0.1 g in 1 mL
DENDRYPHIELLA VINOSA (UNII: 7S6NW5FH8X) (DENDRYPHIELLA VINOSA - UNII:7S6NW5FH8X)	DENDRYPHIELLA VINOSA	0.1 g in 1 mL
CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)	CLADOSPORIUM CLADOSPORIOIDES	0.1 g in 1 mL
MUCOR RACEMOSUS (UNII: 17RH99LQ7G) (MUCOR RACEMOSUS - UNII:17RH99LQ7G)	MUCOR RACEMOSUS	0.1 g in 1 mL
PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239)	PENICILLIUM DIGITATUM	0.02 g in 1 mL
PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z)	PENICILLIUM EXPANSUM	0.04 g in 1 mL
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	0.02 g in 1 mL
CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H)	CLONOSTACHYS ROSEA F. ROSEA	0.02 g in 1 mL
PHOMA EXIGUA VAR. EXIGUA (UNII: 8JAG41IE4M) (PHOMA EXIGUA VAR. EXIGUA - UNII:8JAG41IE4M)	PHOMA EXIGUA VAR. EXIGUA	0.1 g in 1 mL
AUREOBASIDIUM PULLULANS VAR. PULLUTANS (UNII: D1A2NG69CK) (AUREOBASIDIUM PULLULANS VAR. PULLUTANS - UNII:D1A2NG69CK)	AUREOBASIDIUM PULLULANS VAR. PULLUTANS	0.1 g in 1 mL
RHIZOPUS STOLONIFER (UNII: FEE198DK4Q) (RHIZOPUS STOLONIFER - UNII:FEE198DK4Q)	RHIZOPUS STOLONIFER	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5137-1	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 - MOLD MIX 4

molds - mold mix 4 injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-5002
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: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6)	ASPERGILLUS NIGER VAR. NIGER	0.025 g in 1 mL
ASPERGILLUS TERREUS (UNII: QBN8K7055X) (ASPERGILLUS TERREUS - UNII:QBN8K7055X)	ASPERGILLUS TERREUS	0.025 g in 1 mL
CLADOSPORIUM CLADOSPORIOIDES (UNII: 4ZWY20GTGO) (CLADOSPORIUM CLADOSPORIOIDES - UNII:4ZWY20GTGO)	CLADOSPORIUM CLADOSPORIOIDES	0.1 g in 1 mL
PENICILLIUM DIGITATUM (UNII: 1SB49SV239) (PENICILLIUM DIGITATUM - UNII:1SB49SV239)	PENICILLIUM DIGITATUM	0.025 g in 1 mL
PENICILLIUM EXPANSUM (UNII: 1XSC3BB35Z) (PENICILLIUM EXPANSUM - UNII:1XSC3BB35Z)	PENICILLIUM EXPANSUM	0.05 g in 1 mL
PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM (UNII: 3Y1PE1GCIG) (PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM - UNII:3Y1PE1GCIG)	PENICILLIUM CHRYSOGENUM VAR. CHRYSOGENUM	0.025 g in 1 mL
CLONOSTACHYS ROSEA F. ROSEA (UNII: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H)	CLONOSTACHYS ROSEA F. ROSEA	0.025 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65044-5002-1	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 - TRICHOPHYTON MIX

molds - trichophyton mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-5285
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRICHOPHYTON TONSURANS (UNII: JY1BE33I3Y) (TRICHOPHYTON TONSURANS - UNII:JY1BE33I3Y)	TRICHOPHYTON TONSURANS	0.1 g in 1 mL
TRICHOPHYTON RUBRUM (UNII: 2ZAU32517N) (TRICHOPHYTON RUBRUM - UNII:2ZAU32517N)	TRICHOPHYTON RUBRUM	0.1 g in 1 mL
TRICHOPHYTON MENTAGROPHYTES (UNII: 199I7J3JIV) (TRICHOPHYTON MENTAGROPHYTES - UNII:199I7J3JIV)	TRICHOPHYTON MENTAGROPHYTES	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65044-5285-1	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, 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: I5F729WZ2H) (CLONOSTACHYS ROSEA F. ROSEA - UNII:I5F729WZ2H)	CLONOSTACHYS ROSEA F. ROSEA	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5169-1	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 AND SMUTS, ALTERNARIA TENUIS

alternaria tenuis injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-5009
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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5009-1	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 AND SMUTS, ASPERGILLUS FUMIGATUS

aspergillus fumigatus injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-5021
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48) (ASPERGILLUS FUMIGATUS - UNII:X88DF51T48)	ASPERGILLUS FUMIGATUS	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65044-5021-1	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 AND SMUTS, ASPERGILLUS NIGER

aspergillus niger injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-5033
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPERGILLUS NIGER VAR. NIGER (UNII: 9IOA40ANG6) (ASPERGILLUS NIGER VAR. NIGER - UNII:9IOA40ANG6)	ASPERGILLUS NIGER VAR. NIGER	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (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 AND SMUTS, BOTRYTIS CINEREA

botrytis cinerea injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-5049
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BOTRYTIS CINEREA (UNII: TBW53313S7) (BOTRYTIS CINEREA - UNII:TBW53313S7)	BOTRYTIS CINEREA	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-5049-1	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	

Labeler - Jubilant HollisterStier LLC (069263643)

Registrant - Jubilant HollisterStier LLC (069263643)

Revised: 1/2020 Jubilant HollisterStier LLC