CARROT- carrot injection, solution
CASEIN- casein injection, solution
CELERY- celery injection, solution
CHERRY- cherry injection, solution
CHICKEN MEAT- chicken injection, solution
CINNAMON- cinnamon injection, solution
CLAM- northern quahog injection, solution
COCOA BEAN- cocoa injection, solution
COCONUT- coconut injection, solution
CODFISH- atlantic cod injection, solution
COFFEE- coffee bean injection, solution
CRAB- red king crab injection, solution
CUCUMBER- cucumber injection, solution
EGG WHITE- egg white injection, solution
EGG, WHOLE- egg injection, solution
ALK-Abello, Inc.

Food Allergenic Extracts

ALLERGENIC EXTRACTS,

FOR DIAGNOSTIC USE ONLY

DIRECTIONS FOR USE

WARNING

This product is intended for use by physicians who are experienced in the administration of allergenic extracts and the emergency care of anaphylaxis, or for use under the guidance of an allergy specialist.

As with all allergenic extracts, severe systemic reactions may occur. In certain individuals these life-threatening reactions may result in death. Fatalities associated with skin testing have been reported. Patients should be observed for at least 20 - 30 minutes following testing. Emergency measures and adequately trained personnel should be immediately available in the event of a life-threatening reaction.

Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk to a fatal outcome from a systemic allergic reaction.

Sensitive patients may experience severe anaphlactic reactions resulting in respiratory obstruction, shock, coma and/or death. Adverse events are to be reported to MedWatch (1-800-FDA-1088), Adverse Event Reporting, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787. This product should not be injected intravenously. Patients receiving beta blockers may not be responsive to epinephrine or inhaled bronchodilators. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require theophylline, oxygen, intubation and the use of life support systems. Parenteral fluid and/or plasma expanders may be utilized for the treatment of shock. Adrenocorticosteroids may be administered parenterally or intravenously. Refer to WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections below.

Port Washington, NY 11050

U.S. Government License No. 1256

DESCRIPTION

Sterile diagnostic extracts are supplied in either phenol-saline diluent for Intradermal Testing or in diluent containing glycerin 50% (v/v) for Percutaneous Testing and phenol 0.4% (preservative). Inactive ingredients may include: sodium chloride for isotonicity, glycerin, and sodium bicarbonate as a bufferPollens are individually extracted from pure pollen extracted in a phenol-preserved sodium bicarbonate solution. Short Ragweed and Mixed (Tall and Short) Ragweed extracts are standardized by Antigen E content and so labeled. The Antigen E content of extracts containing Short Ragweed at a concentration more dilute than a weight/volume ratio of 1:10 are obtained by calculating the Antigen E content based on the assay value of more concentrated extract. Pollen extracts are filtered aseptically and after final packaging, they are tested for sterility and safety. Molds are individually extracted from pure powdered inactivated mold source material extracted in phenol preserved saline.Mold extracts are filtered aseptically and after final packaging are tested for sterility and safety.

Molds (fungi) are present in all inhabited places at all seasons of the year; they are so ubiquitous that they are prevalent at times when common allergic pollens and other inhalants are not. In the home and surroundings, molds are found in upholstered furniture, mattresses, drapes, cellar and storage room dust, woolens, leather goods, fruits, meats, cheeses, garden soil and on plants. Spores, mycelial fragments and mold residues are thus inhaled, contacted and ingested continuously.

Foods, miscellaneous inhalants and epidermals are individually extracted in phenol preserved saline or glycerin, filtered aseptically and after final packaging are tested for sterility and safety.

CLINICAL PHARMACOLOGY

Diagnostically (for skin testing) the allergen combines with IgE antibodies fixed to mast cells in the skin. This complexing causes an increase in cellular permeability and degranulation of the mast cells releasing chemical mediators. These mediators (such as histamine) are responsible for a local inflammatory response of wheal and erythema typical of a positive skin test reaction and also, the symptoms commonly associated with allergic disease.[1] The more mediator release, the larger the reaction (wheal and erythema).

INDICATIONS AND USAGE

These products are for diagnostic use only. Diagnostic allergenic extracts are indicated for use in skin testing to establish the clinical relevance of specific allergens to which the patient has been exposed. By measuring skin test response the physician may assess the degree of sensitivity that patients have to the allergens. For extracts standardized in AU and BAU, see individual directions for use. **Allergenic extracts for diagnostic use only of coffee, mosquito, cottonseed, and flaxseed have not been shown by adequate data to be safe and effective for therapeutic use.**

CONTRAINDICATIONS

Patients on beta blockers can be non-responsive to beta agonists that may be required to reverse a systemic reaction (also, see **boxed WARNING** statement and **ADVERSE REACTIONS**). The physician should carefully weigh the benefit derived from skin testing vs. the risk to the patient should a systemic reaction arise.

Patients with unstable asthma or steroid dependent asthmatics and patients with underlying cardiovascular disease are at greater risk to a fatal outcome from a systemic allergic reaction[2,3]. See also **PRECAUTIONS** and **ADVERSE REACTIONS**.

WARNING

Patients should always be observed for at least 20 - 30 minutes after skin testing. In the event of a marked systemic reaction such as urticaria, angioedema, wheezing, dyspnea, respiratory obstruction, hypotension, coma and death (see **ADVERSE REACTIONS**), applications of a tourniquet above the injection site and administration of 0.2 mL to 1 mL (0.01 mg/kg) of epinephrine injection (1:1,000) are recommended. Maximal recommended dose for children between 2 and 12 years of age is 0.5 mL. The tourniquet is then gradually released at 15 minute intervals. Patients under treatment with beta blockers may be refractory to the usual dose of epinephrine.

Volume expanders and vasopressor agents may be required to reverse hypotension, inhalation bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. In case of respiratory obstruction, oxygen and intubation may be necessary. Life-threatening reactions unresponsive to the above may require cardiopulmonary resuscitation.

PRECAUTIONS

INFORMATION FOR PATIENTS:

Patients should be instructed to describe any active allergic symptoms such as rhinitis, wheezing, dyspnea, etc. prior to testing. Also, see **ADVERSE REACTIONS** and **WARNINGS** Sections.

Patients should always be observed 20 to 30 minutes after testing.

General:

1. In the presence of active symptoms such as rhinitis, wheezing, dyspnea, etc., the indications for skin testing must be weighed carefully against the risk of temporarily aggravating the symptoms by the testing itself. Objective assessment of pulmonary function such as Peak Expiratory Flow Rate (PEFR) before allergen administration and prior to discharge may be useful in unstable asthmatics to reduce the chances of exacerbation of the patient's asthma. Patients should be instructed to describe any active allergic symptoms as described above prior to skin testing and encouraged to report any late reactions from this testing. Also, see **ADVERSE REACTIONS** and **WARNING** sections.
2. Store allergenic extracts between 2°-8°C at all times, even during use.
3. Care must be taken to avoid drawing blood.
   A. For percutaneous testing, if blood is observed, immediately wipe the allergen from the site.
   B. For intradermal skin testing, pull gently on the syringe plunger and note if any blood enters the syringe. If blood is obtained, reposition the needle and repeat before injecting (see **DOSAGE AND ADMINISTRATION**).
4. Allergenic extracts become less potent with age. Allergenic extracts containing glycerin 50% v/v are relatively stable. Non-glycerinated aqueous extracts, particularly dilute forms as used for intradermal skin testing, have been shown to be extremely unstable. Until such time as stability studies are complete with dilute allergens, new intradermal strength materials should be prepared every few weeks.
5. Use standard aseptic precautions if making dilutions from stock concentrates to intradermal strength.
6. For intradermal testing: Extracts in glycerin 50% v/v must be diluted with a non-glycerinated diluent and must be diluted at least 25-fold to less than 2% glycerin by volume, as glycerin above this level can cause false positive intradermal skin test results.

Pregnancy - Category C:

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.

Controlled studies of hyposensitization with moderate to high doses of allergenic extracts during conception and all trimesters of pregnancy have failed to demonstrate any risk to the fetus or to the mother[4]. However, on the basis of histamine's known ability to contract the uterine muscle, the release of significant amounts of histamine from allergen exposure to skin test overdose should be avoided on theoretical grounds. Therefore, allergenic extracts should be used cautiously in a pregnant woman and only if clearly needed.

Pediatric Use:

Allergenic extracts for diagnostic use have been given safely in infants and young children. Infants have lower skin test reactivity to histamine, as well as common allergens. Skin test reactivity gradually increases to age 6 and plateaus to age 60. Therefore, small skin test reactions should be anticipated in children under age 6.

Geriatric Use:

Skin test reactivity gradually decreases after age 60. Therefore, smaller skin test reactions should be anticipated in adults over age 60.

Nursing Mothers:

It is not known if allergens administered subcutaneously appear in human milk. Because many drugs are excreted in human milk, caution should be exercised when allergenic extracts are administered to a nursing woman.

Carcinogenesis, mutagenesis, impairment of fertility:

Studies in animals have not been performed.

Drug Interactions:

Drugs can interfere with the performance of skin tests[5].

Antihistamines: Response to mediator (histamine) released by allergens is suppressed by antihistamines. The length of suppression varies and is dependent on individual patient, type of antihistamine and length of time the patient has been on antihistamines. The duration of this suppression may be as little as 24 hours (chlorpheniramine), and can be as long as 40 days (astemizole).

Tricyclic Antidepressants: These exert a potent and sustained decrease of skin reactivity to histamine which may last for a few weeks.

$Beta_2$ Agonists: Oral terbutaline and parenteral ephedrine, in general, have been shown to decrease allergen induced wheal.

Dopamine: Intravenous infusion of dopamine may inhibit skin test responses.

Beta Blocking Agents: Propranolol can significantly increase skin test reactivity.

Other Drugs: Short acting steroids, inhaled $beta_2$ agonists, theophylline and cromolyn do not seem to affect skin test response.

ADVERSE REACTIONS

Fatalities from skin testing in the United States have been extensively reviewed by Lockey.[2] Six fatalities were associated with intradermal testing without previous percutaneous testing and one was associated with a combination of percutaneous (scratch) and intradermal skin testing. With careful attention to dosage and administration, fatal reactions occur infrequently, but it must be remembered that allergenic extracts are highly potent to sensitive individuals and overdosage could result in anaphylactic symptoms. Therefore it is imperative that physicians administering allergenic extracts for skin testing understand, and be prepared for the treatment of severe reactions.

Local:

Immediate wheal and erythema reactions are to be expected; but if very large, may be the first manifestation of a systemic reaction. In such cases, immediately wipe the test site(s) with sterile gauze or cotton to remove excess allergen.

Systemic Reactions:

Systemic reactions are characterized by one or more of the following symptoms: sneezing, mild to severe generalized urticaria, itching (other than at the skin test site), extensive or generalized edema, wheezing, asthma, dyspnea, cyanosis, hypotension, syncope, and upper airway obstruction. Symptoms may progress to shock and death. Patients should always be observed for at least 20 - 30 minutes after testing.

Volume expanders and vasopressor agents may be required to reverse hypotension. Inhalational bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. Severe airway obstruction unresponsive to bronchodilator may require tracheal intubation and use of oxygen. In the event of a marked systemic reaction, application of a tourniquet above the injection site and the administration of 0.2 mL to 1.0 mL of epinephrine injection (1:1,000) is recommended. Maximum recommended dose for children between 2 and 12 years of age is 0.3 mL. The tourniquet should not be left in place without loosening for 90 seconds every 15 minutes.

Adverse events should be reported via MedWatch (1-800-FDA-1088), Adverse Event Reporting, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

OVERDOSAGE

Signs and symptoms of overdose are typically large local and systemic reactions. For management of overdose reactions, refer to the ADVERSE REACTIONS section above.

DOSAGE AND ADMINISTRATION

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

Skin test techniques for immediate (Type I) hypersensitivity testing fall into two major categories: percutaneous, and intracutaneous.

Percutaneous techniques:

For percutaneous testing, in general, skin is scratched, punctured or pricked just before the allergen is applied or through a drop of test allergen. There are several devices available for this technique. Refer to the manufacturer or distributor’s circular for specific directions for their use.

In General:

1. It is recommended that the test areas should be placed no closer than 4 - 5 cm apart to avoid interference of reactions when several tests are applied.
2. Skin test areas should be cleansed with alcohol and air dried.
3. Preferably, the allergen should be placed on the volar surface of the forearm, upper arm, or the patient’s back. The patient should be placed in a comfortable position prior to testing.
4. For scratch testing, a sharp, clean, sterile instrument is used to abrade the skin, but not to draw blood. Each scratch should be about 2 - 4 mm in length. A small drop of extract is placed on the surface of the skin.
5. Prick testing: For prick testing, a sharp, sterile instrument is used to puncture the skin slightly, applying it at a 15 - 20° angle to the skin. The instrument is gently raised, “tenting” the skin until it pops out, generally pricking through the drop of allergen. Do not draw blood.

6. For puncture testing, a sharp, clean, sterile instrument must be used. Puncture the skin, through the drop of allergen, perpendicular to the skin. Do not draw blood.

For all of the above techniques, a separate instrument must be used for each patient; if the instrument is to be used to pass through the allergen, to avoid cross-contamination, a separate instrument is to be used for each allergen. The test should be read in 15 minutes, measuring both wheal size and erythema.

Intracutaneous (intradermal) testing:

General: Intradermal testing is more sensitive than percutaneous testing and its specificity is dependent on dose. Intradermal testing is not intended as an initial screen unless used in highly dilute solutions. Intradermal testing is usually reserved for allergens that have demonstrated either negative or equivocal percutaneous skin test response in the face of positive or unclear history.

Intradermal testing of one allergen in several serial dilutions (beginning with the weakest to the more concentrated dilutions) may also be useful in assessing degree of patient sensitivity for the establishment of a safe starting dose for immunotherapy.

Bulk extracts must be diluted for intradermal testing. Use of Sterile Diluent for Allergenic Extracts or Sterile Diluent for Allergenic Extracts Normal Saline with HSA (albumin saline) is recommended. Dilutions should be made with sterile disposable syringes using aseptic technique. Commonly 10 fold dilutions are used to achieve a desired concentration for intradermal testing and continuation of immunotherapy. For example, transferring 0.5 mL of a 10,000 PNU/mL extract into 4.5 mL of diluent will yield 5 mL of extract at 1,000 PNU/mL. For weight volume products, a 1:100 w/v dilution may be prepared from a 1:10 w/v by transferring 0.5 mL of the 1:10 w/v to 4.5 mL of dilutent. Prepare as many additional serial dilutions as necessary to reach the appropriate concentration. As a general rule intradermal strength should begin at no higher than 1/100 to 1/1000 of the percutaneous strength that resulted in a negative skin test reaction.

1. It is recommended that the test areas should be spaced no less than 5 cm apart to avoid interference with adjacent allergen or control.
2. Skin should be cleansed with alcohol and air dried.
3. A sterile 1 mL or 1/2 mL syringe with a 26 - 30 gauge needle should be used. A separate sterile syringe should be used for each extract and each patient.
4. Care should be taken to eliminate air bubbles from the syringe prior to injecting the test dose. It is suggested that not more than 6 - 10 allergens of each different type be used at any one time. Very sensitive patients may show rapid response.
5. The skin is held tensely, and the needle is inserted almost parallel to the skin, beveled side up far enough to cover the beveled portion. Slowly inject sufficient extract to make a small bleb of approximately 5 mm in diameter (0.01 - 0.02 mL).
6. Read the test results in 15 minutes.

Selection of the proper strength for intracutaneous testing: A general rule for the prevention of untoward reactions, particularly in extremely sensitive patients, is to screen by percutaneous methods initially, and begin intradermal testing at a strength not more than 1/100 of a negative or equivocal percutaneous reaction.

Controls:

In both percutaneous and intracutaneous tests, a negative control test with diluent alone should be performed because some patients exhibit dermographia, and/or other non-specific irritant responses.

As a positive control in the evaluation of allergenic skin testing, histamine 1 mg/mL (histamine base) should be used for percutaneous testing, and histamine 0.1 mg/mL (histamine base) should be used for intradermal testing.

Interpretation of results:

Patient’s response is graded on the basis of the size of erythema or wheal.[6] General guidelines follow

for percutaneous testing, different devices and/or techniques influence the size of the reaction, therefore it is important to refer to the device manufacturer's or distributor's instructions when grading reactions.

Percutaneous (prick or scratch) test:

0 No reaction or less than control.

+ Erythema greater than control, smaller than a nickel (21 mm diameter).

++ Erythema greater than a nickel in diameter, no wheal.

+++ Wheal and erythema without pseudopods.

++++ Wheal and erythema with pseudopods.

Intradermal test:

0 No reaction or less than negative control.

+ 3-4 mm wheal with erythema, or erythema alone larger than a nickel (21 mm diameter).

++ 4-8 mm wheal and erythema, without pseudopods.

+++ Over 8 mm wheal and erythema without pseudopods.

++++ Wheal and erythema with pseudopods.

HOW SUPPLIED

For scratch and prick testing: 5 mL dropper applicator vials in 50% v/v glycerin or 10mL stoppered vial in 50% v/v glycerin. Available individually and in a complete set of the most common allergens. Available in either Protein Nitrogen Units (PNU/mL) or weight to volume (w/v).

For intracutaneous testing: 5 mL sterile vials, aqueous based, individually and in a complete set of the most common allergens. Available in either Protein Nitrogen Units (PNU/mL) or weight to volume (w/v).

Histatrol® Positive skin test control - histamine. 1 mg/mL and 0.1 mg/mL histamine base.

See Product Catalog for specific diagnostic concentrations available.

STORAGE

To maintain stability of allergenic extracts, proper storage conditions are essential. Bulk concentrates and diluted extracts are to be stored at 2º to 8°C even during use. Bulk or diluted extracts are not to be frozen. Do not use after the expiration date shown on the vial label.

REFERENCES

1. Holgate, S.T., Robinson, C. and Church, M.K. Mediators of immediate hypersensitivity. In Middleton et al: *Allergy Principles and Practice,* St. Louis, 1988, C.V. Mosby, p 135.
2. Lockey, R.F., et al. Fatalities from immunotherapy (IT) and skin testing (ST). J. Allergy Clin. Immunol. 1987: 79: 660.
3. Reid, M.J. et al. Survey of fatalities from skin testing and immunotherapy. 1985-1989. J. Allergy Clin Immunol. 1993; 92:6.
4. DeBuske L. M. et al. Special problems regarding Allergen Immunotherapy in Immunology and Allergy Clinics of North America, Greenburger, P.A. Ed. February 1992; 145-149.
5. Bousquet, J. In vivo methods for the study of allergy: skin test, techniques and interpretation. In: Middleton et al.: Allergy Principles and Practice 3rd Ed. St. Louis: CV Mosby, 1988:167.
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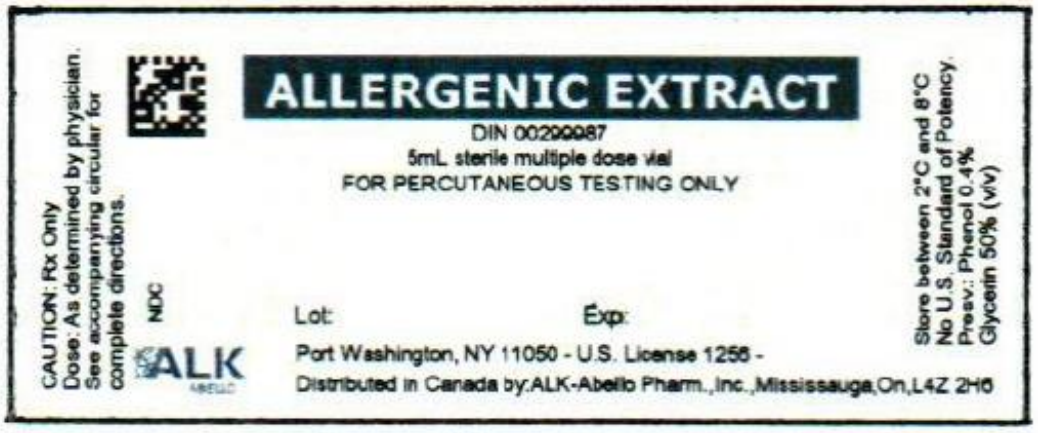
Distributed in Canada by:
ALK-Abelló Pharmaceuticals, Inc.
#35-151 Brunel Road
Mississauga, Ontario
Canada L4Z 2H6

PRINCIPAL DISPLAY PANEL

ALLERGENIC EXTRACT
DIN 00299987
5mL sterile multiple dose vial
FOR PERCUTANEOUS TESTING ONLY



CARROT

carrot injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6116
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARROT (UNII: L56Z1JK48B) (CARROT - UNII:L56Z1JK48B)	CARROT	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL

HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6116-10	10 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	BLA103753	02/23/1998	

CASEIN

casein injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6118
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CASEIN (UNII: 48268V50D5) (CASEIN - UNII:48268V50D5)	CASEIN	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6118-10	10 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	BLA103753	02/23/1998	

CELERY

celery injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6120
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CELERY (UNII: 44IDY6DTKX) (CELERY - UNII:44IDY6DTKX)	CELERY	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-6120-10	10 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	BLA103753	02/23/1998	

CHERRY

cherry injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6121
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CHERRY (UNII: BUC5I9595W) (CHERRY - UNII:BUC5I9595W)	CHERRY	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-6121-10	10 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	BLA103753	02/23/1998	

CHICKEN MEAT

chicken injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6122
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHICKEN (UNII: 0X8Q245Y7B) (CHICKEN - UNII:0X8Q245Y7B)	CHICKEN	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6122-10	10 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	BLA103753	02/23/1998	

CINNAMON

cinnamon injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:0268-6123
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CINNAMON (UNII: 5S29HWU6QB) (CINNAMON - UNII:5S29HWU6QB)	CINNAMON	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6123-10	10 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	BLA103753	02/23/1998	

CLAM

northern quahog injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6124
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NORTHERN QUAHOG (UNII: D6G49OV9IM) (NORTHERN QUAHOG - UNII:D6G49OV9IM)	NORTHERN QUAHOG	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-6124-10	10 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	BLA103753	02/23/1998	

COCOA BEAN

cocoa injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6125
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
COCOA (UNII: D9108TZ9KG) (COCOA - UNII:D9108TZ9KG)	COCOA	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6125-10	10 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	BLA103753	02/23/1998	

COCONUT

coconut injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6127
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCONUT (UNII: 3RT3536DHY) (COCONUT - UNII:3RT3536DHY)	COCONUT	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6127-10	10 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	BLA103753	02/23/1998	

CODFISH

atlantic cod injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6128
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATLANTIC COD (UNII: RPX7J99EXW) (ATLANTIC COD - UNII:RPX7J99EXW)	ATLANTIC COD	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6128-10	10 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	BLA103753	02/23/1998	

COFFEE

coffee bean injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6129
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
COFFEE BEAN (UNII: JFH385Y744) (COFFEE BEAN - UNII:JFH385Y744)	COFFEE BEAN	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-6129-10	10 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	BLA103753	02/23/1998	

CRAB

red king crab injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6130
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RED KING CRAB (UNII: E88KKF623O) (RED KING CRAB - UNII:E88KKF623O)	RED KING CRAB	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL

HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6130-10	10 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	BLA103753	02/23/1998	

CUCUMBER

cucumber injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6132
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CUCUMBER (UNII: YY7C30VXJT) (CUCUMBER - UNII:YY7C30VXJT)	CUCUMBER	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0268-6132-10	10 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	BLA103753	02/23/1998	

EGG WHITE

egg white injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6133
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
EGG WHITE (UNII: 3E0I92Z2GR) (EGG WHITE - UNII:3E0I92Z2GR)	EGG WHITE	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-6133-10	10 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	BLA103753	02/23/1998	

EGG, WHOLE

egg injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:0268-6135
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

EGG (UNII: 291P45F896) (EGG - UNII:291P45F896)	EGG	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 1 mL
PHENOL (UNII: 339NCG44TV)	0.004 mL in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.009 g in 1 mL
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	0.0027 g in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0268-6135-10	10 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	BLA103753	02/23/1998	

Labeler - ALK-Abello, Inc. (809998847)

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