POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS- sagebrush, mugwort artemisia vulgaris injection, solution
POLLENS - WEEDS AND GARDEN PLANTS, SCALE, WING SHAD ATRIPLEX CANESCENS- scale, wing shad atriplex canescens injection, solution
POLLENS - WEEDS AND GARDEN PLANTS, SCOTCH BROOM CYTISUS SCOPARIUS- scotch broom cytisus scoparius injection, solution
POLLENS - WEEDS AND GARDEN PLANTS, SORREL, SHEEP RUMEX ACETOSELLA- sorrel, sheep rumex acetosella injection, solution
POLLENS - WEEDS, CARELESS WEED AMARANTHUS PALMERI- careless weed amaranthus palmeri injection, solution
POLLENS - WEEDS, CARELESS/PIGWEED MIX- careless/pigweed mix injection, solution
POLLENS - WEEDS, DOCK/SORREL MIX- pollens - weeds, dock/sorrel mix injection, solution
POLLENS - WEEDS, GIANT, SHORT, WESTERN RAGWEED MIX- giant, short, western ragweed mix injection, solution
Jubilant HollisterStier LLC

ALLERGENIC EXTRACTS IN BULK VIALS

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.1

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, be observed in the office for at least 30 minutes after skin testing or treatment, and be cautioned to contact the physician's office if symptoms occur. See ADVERSE REACTION section of this package insert regarding adverse event reporting.
Standardized glycerinated extracts may be more potent than regular extracts and therefore are not directly interchangeable with non-standardized extracts, or other manufacturers' products.
Patients with cardiovascular diseases and/or pulmonary diseases such as symptomatic unstable, steroid dependent asthma, and/or those 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 allergy treatment regimen. Patients should be treated only if the benefit of treatment outweighs the risks.1
Patients on 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. 2
This product should never be injected intravenously.
Refer to the WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and OVERDOSE Sections for further discussion.

DESCRIPTION

The allergenic extract in this vial is referred to as a "bulk" extract or stock concentrate since it is designed primarily for the physician equipped to prepare dilutions and mixtures as required. The extract is sterile and intended for subcutaneous injection for immunotherapy and scratch, prick or puncture for diagnosis. Unless specified otherwise, the concentration of extract supplied will in most cases be

expressed in weight to volume (e.g., 1:10 or 1:20 w/v) and will be the strongest available. Where mixtures of pollens and non-pollens have been ordered, the mixed extract will be treated as a pollen mixture. To insure maximum potency for the entire dating period, all bulk concentrates will contain 50% volume to volume (v/v) glycerin unless otherwise requested. Dilutions will also be prepared with 50% (v/v) glycerin unless another diluent is specified.

Source materials utilized in allergenic extract products include pollens, molds, animal epidermals, insects, foods and environmental materials.

Pollens are collected using techniques such as waterset or vacuuming, cleaned and purified to greater than 99% single specie pollen (less than 1% foreign particle presence).

Molds are typically grown on synthetic nutrient medias and are derived from the surface growth (mycelia).

Animal source materials are collected from animals deemed to be healthy at the time of collection by a veterinarian or individual trained and certified by a veterinarian. Epidermals include feathers, hair and dander, or the whole epidermal (pelt) as described on product labeling.

Regular process epidermals are extractions of the source material without additional processing, except that certain materials are defatted. AP™ (acetone precipitated) epidermal source materials are derived from the precipitate formed when acetone is added to an aqueous extract. The resulting precipitate is dried, and becomes the source material for the AP™ product.

Insects are collected in whole body form. Extractions take place as whole body or ground insects.

Information on Foods and other Environmental source materials can be obtained by contacting our Customer Service Department.

The following is a brief summary of the six methods of describing allergenic product concentration.

1. Weight to volume (w/v). Weight to volume (w/v) describes the weight of allergenic source material added to a given volume of extracting fluid. A 1:10 w/v extract, e.g., indicates that the solution contains the extractable material from one gram of raw material added to each 10 mL Glycero-Coca's or 10 mL Coca's extracting fluid. The amount and composition of extracted materials will vary with the type of antigen, the extracting fluid, duration of extraction, pH, temperature, and other variables. Pollens are typically extracted at a 1:20 w/v ratio in Glycero-Coca's while Coca's extracts are 1:10 w/v. Epidermal, environmental, regular molds and insect products are typically extracted at 1:10 w/v. AP™ (acetone precipitated) epidermal products are prepared at a 1:50 w/v concentration (i.e., 1 gram of dried precipitate in 50 mL of reconstitution fluid). AP™ Dog Hair-Dander is prepared at 1:100 w/v concentration. (i.e., 1 gram of dried precipitate in 100 mL of reconstitution fluid.)

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 is reproducible from lot to lot. The amount of protein nitrogen extracted from the source material is influenced by such factors as the type of antigen, the extracting fluid, duration of extraction, pH, temperature and other variables. Allergenic materials make up a variable proportion of the total protein of an extract. Most allergenic extracts are assayed for PNU. Specific PNU information is available upon request.

3. Amb a 1. Of the many allergens from Short Ragweed which have been purified and characterized [Amb a 1 3 (also known as Antigen E), Amb a 2 3 (also known as Antigen K), Ra3 4, Ra4 (BPA-R) 5, Ra5 6, Ra6, Ra7, Ra87, and cytochrome C 8], Amb a 1 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. A Short Ragweed pollen extracted at 1:20 (w/v) usually assays within a range of 50,000 to 70,000 PNU/mL and 100 to 300 units of Amb a 1 per mL.

The Amb a 1 concentration of any Short Ragweed extract which is diluted with a diluent or other allergenic extracts is determined by calculation. The resulting Amb a 1 value does not reflect the total

potency of the product if Short Ragweed extract is mixed with another allergenic extract.

4. Allergy Units per mL (AU/mL). The potency of extracts labeled in Allergy Units (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). Other standardized allergenic extracts are labeled in Bioequivalent Allergy Units/mL (BAU/mL) based on their comparison (by in vitro assay or major allergen content) to CBER, FDA Reference Preparations. The FDA reference extracts have been assigned Bioequivalent Allergy Units based on the CBER ID_{50}EAL method.9 Briefly, highly sensitive patients are skin tested to the reference preparation using an intradermal technique employing 3-fold extract dilutions. Depending on the dilution which elicits a summation of erythema diameter of 50, Bioequivalent Allergy Units are assigned as follows:

BAU/mL	D_{50} Range
100,000	13.9 - 15.9
10,000	10.9 - 12.9
1,000	8.8 - 10.8
100	6.7 - 8.7

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.

e.g. **Concentrate**
50% Short Ragweed 1:20 w/v
25% Std. Cat Pelt 10,000 BAU/mL
25% Mite D. farinae 10,000 AU/mL

Should the physician choose to calculate the actual strength of each component in the "Concentrate" mixture, the following formulation may be used:

Actual Allergen Strength in Concentrate	=	**Allergen Manufacturing Strength**	X	**% Allergen in Formulation (by volume or parts)**

Ingredients: Active ingredients are the allergen(s) noted on the vial label. Preservative is 50% (v/v) glycerin, or 0.4% phenol, as indicated on the vial label. Additional ingredients are 0.5% sodium chloride, and 0.275% sodium bicarbonate.

CLINICAL PHARMACOLOGY

The mechanism by which hyposensitization is achieved is not known completely. It has been shown that repeated injections of appropriate allergenic extracts will ameliorate the intensity of allergic symptoms upon contact with the allergen.11, 12, 13, 14 Clinical studies which address the efficacy of immunotherapy are available. The allergens which have been studied are cat, mite, and some pollen extracts.10, 15, 16, 17, 18, 19

IgE antibodies bound to receptors on mast cell membranes are required for the allergic reaction, and their level is probably related to serum IgE concentrations. Immunotherapy has been associated with decreased levels of IgE, and also with increases in allergen specific IgG "blocking" antibody.
The histamine release response of circulating basophils to a specific allergen is reduced in some patients by immunotherapy, but the mechanism of this change is not clear.

Further study and clarification of the relationships among changes in blocking antibody, reaginic antibody, and mediator-releasing cells, and between these three factors and successful immunotherapy, is needed.

INDICATIONS AND USAGE

20,21,22,23

Allergenic extracts are indicated for use in diagnosis and immunotherapy of patients presenting symptoms of allergy (hay fever, rhinitis, etc.) to specific environmental allergens. The selection of allergenic extracts to be used should be based on a thorough and carefully taken history of hypersensitivity, and confirmed by skin testing.

The use of mixed or unrelated antigens for skin testing is not recommended since, in the case of a positive reaction, it does not indicate which component of the mix is responsible for the reaction, while, in the case of a negative reaction, it fails to indicate whether the individual antigens at full concentration would give a positive reaction. Utilization of such mixes for compounding a treatment may result, in the former case, in administering unnecessary antigens and, in the latter case, in the omission of a needed antigen.

Avoidance of allergens is to be advocated if possible, but cannot always be attained, e.g., allergy to dog dander in kennel owners and employees, dog breeders, research workers, veterinarians, etc.

Allergens to which a patient is extremely sensitive should not be included in treatment mixes with allergens to which there is much less sensitivity, but should be administered separately. This allows individualized and better control of dosage increases, including adjustments in dosage becoming necessary after severe reactions which may occur with the highly reactive allergen.

CONTRAINDICATIONS

There are no known absolute contraindications to immunotherapy. See PRECAUTIONS and WARNINGS.

Patients with cardiovascular diseases and/or pulmonary diseases such as symptomatic unstable, steroid-dependent asthma, and/or those 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 allergy treatment regimen. Patients should be treated only if the benefit of treatment outweighs the risks.1

Treat patients only with allergens to which they are allergic by skin test reaction, have a history of symptoms on exposure, and are likely to be exposed to again.

Any injections, including immunotherapy, should be avoided in patients with a bleeding tendency.

Patients on 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 systemic reactions.2

Since there are differences of opinion concerning the possibility of routine immunizations exacerbating autoimmune diseases, immunotherapy should be given cautiously to patients with other immunologic diseases and only if the risk from exposure is greater than the risk of exacerbating the underlying disorder.

WARNINGS

See WARNINGS box at the beginning of this package insert. See also PRECAUTIONS.

Allergenic extracts must be temporarily withheld from patients or the dose adjusted downward if any of the following conditions exist: (1) severe symptoms of rhinitis and/or asthma; (2) infection or flu accompanied by fever; (3) any evidence of an excessively large local or any generalized reaction during the initial stages of immunotherapy or during maintenance therapy, and/or (4) exposure to excessive amounts of clinically relevant allergen prior to a scheduled injection. Do not administer immunotherapy during a period of symptoms due to exposure. Since the individual components of the

extract are those to which the patient is allergic, and to which s/he will be exposed, typical allergic symptoms may follow shortly after the injection, particularly when the antigen load from exposure plus the injected antigen exceeds the patient's antigen tolerance.
THE CONCENTRATE MUST NOT BE INJECTED AT ANY TIME UNLESS TOLERANCE HAS BEEN ESTABLISHED. DILUTE CONCENTRATED EXTRACTS WITH STERILE DILUENT FOR SKIN TESTING AND IMMUNOTHERAPY.
INJECTIONS MUST NEVER BE GIVEN INTRAVENOUSLY. Subcutaneous injection is recommended. Intracutaneous or intramuscular injection may produce large local reactions or be excessively painful.
AFTER INSERTING NEEDLE SUBCUTANEOUSLY, BUT BEFORE INJECTING, ALWAYS WITHDRAW THE PLUNGER SLIGHTLY. IF BLOOD APPEARS IN THE SYRINGE, CHANGE NEEDLE AND GIVE THE INJECTION IN ANOTHER SITE.

IF CHANGING TO A DIFFERENT LOT OF EXTRACT: All extracts lose potency over time, and a fresh extract could have an effective potency that is substantially greater than that of the old extract. Even though it is the same formula and concentration, the first dose from the new vial should not exceed 50% of the previous dose.
IF THE EXTRACT PREVIOUSLY USED WAS FROM ANOTHER MANUFACTURER: Since manufacturing processes and sources of raw materials differ among manufacturers, the interchangeability of extracts from different manufacturers cannot be insured. The starting dose of the extract therefore should be greatly decreased even though the extract is the same formula and dilution. In general, a dose reduction to 50% of the previous product dose should be adequate, but each situation must be evaluated separately considering the patient's history of sensitivity, tolerance of previous injections, and other factors. If the patient tolerates a 50% decrease, the next dose could be raised to the previous dose amount. If the decrease is greater than 50%, the next dose would need to be determined by the allergist, depending on the situation. Dose intervals should not exceed one week when rebuilding dose. See DOSAGE AND ADMINISTRATION.
IF A PROLONGED PERIOD OF TIME HAS ELAPSED SINCE THE LAST INJECTION: Patients may lose tolerance for allergen injections during prolonged periods between doses. The duration of tolerance is an individual characteristic and varies from patient to patient. In general, the longer the lapse in the injection schedule, the greater dose reduction required. If the interval since last dose is over four weeks, perform skin tests to determine starting dose. See DOSAGE AND ADMINISTRATION.
IF THE PREVIOUS EXTRACT WAS OUTDATED: The dating period for allergenic extracts indicates the time that they can be expected to remain potent under refrigerated storage conditions (2° - 8°C). During the storage of extracts, even under ideal conditions, some loss of potency occurs. For this reason, extracts should not be used beyond their expiration date. If a patient has been receiving injections of an outdated extract, s/he may experience excessive local or systemic reactions when changed to a new and possibly more potent extract. In general, the longer the material has been outdated, the greater the dose reduction necessary for the fresh extract.
IF CHANGING FROM ALUM-ADSORBED TO AQUEOUS OR GLYCERINATED EXTRACTS: When the patient was previously receiving alum-adsorbed or alum-precipitated extract, the safest course is to start over as though the patient had not been receiving immunotherapy. See DOSAGE AND ADMINISTRATION and ADVERSE REACTIONS.
IF ANY OTHER CHANGES HAVE BEEN MADE IN THE EXTRACT CONCENTRATE FORMULA: Changes other than those listed above may include situations such as a redistribution of component parts or percentages, a difference in extracting fluid (i.e., change from non-glycerin extracts to 50% glycerin extracts), combining two or more stock concentrates, or any other change. It should be recognized that any change in formula can affect a patient's tolerance of the treatment. The usual 1/2 of the previous dose for a new extract may produce an adverse reaction; extra dilutions are recommended whenever starting a revised formula. The greater the change, the greater the number of dilutions required.

Proper selection of the dose and careful injection should prevent most systemic reactions. It must be remembered that allergenic extracts are highly potent in sensitive individuals, and that systemic reactions of varying degrees of severity may occur, including urticaria, rhinitis, conjunctivitis, wheezing, coughing, angioedema, hypotension, bradycardia, pallor, laryngeal edema, fainting, or even anaphylactic shock and death, as described under ADVERSE REACTIONS. Patients should be informed of this, and the precautions should be discussed prior to immunotherapy. (See PRECAUTIONS.) Severe systemic reactions should be treated as indicated in ADVERSE REACTIONS. Refer to WARNINGS box.

PRECAUTIONS

1. General

The presence of asthmatic signs and symptoms appear to be an indicator for severe reactions following allergy injections. An assessment of airway obstruction either by measurement of peak flow or an alternate procedure may provide a useful indicator as to the advisability of administering an allergy injection.1, 24, 25, 26, 27

Concentrated extracts must not be injected unless tolerance has been established. Concentrated extracts must be diluted prior to use: See DOSAGE and ADMINISTRATION for detailed instructions on the dilution of allergenic extracts.

Any evidence of a local or generalized reaction requires a reduction in dosage during the initial stages of immunotherapy, as well as during maintenance therapy.
Allergenic extracts diluted with sterile Albumin Saline with Phenol (0.4%) may be more potent than extracts diluted with diluents which do not contain stabilizers. When switching from non-stabilized to stabilized diluent, consider weaker initial dilutions for both intradermal testing and immunotherapy.
Sterile solutions, vials, syringes, etc. should be used and aseptic precautions observed in making dilutions.
To avoid cross-contamination, do not use the same needle to withdraw materials from vials of more than one extract, or extract followed by diluent.
A sterile tuberculin syringe graduated in 0.01 mL units and with a needle at least 5/8" long should be used to measure each dose from the appropriate dilution.
Aseptic techniques should always be employed when injections of allergenic extracts are being administered. A separate sterile syringe should be used for each patient to prevent transmission of hepatitis and other infectious agents from one person to another.
Patient reactions to previous injections should be reviewed before each new injection, so that dosage can be adjusted accordingly. See ADVERSE REACTIONS and WARNINGS.
Rarely, a patient is encountered who develops systemic reactions to minute doses of allergen and does not demonstrate increasing tolerance to injections after several months of treatment. If systemic reactions or excessive local responses occur persistently at very small doses, efforts at immunotherapy should be stopped.
PATIENTS SHOULD BE OBSERVED IN THE OFFICE FOR AT LEAST 30 MINUTES AFTER SKIN TESTING AND EACH TREATMENT INJECTION. Most severe reactions will occur within this time period, and rapid treatment measures should be instituted. See ADVERSE REACTIONS for such treatment measures.
In order to avoid darkening and possible precipitation, do not dilute the following extracts with solutions containing phenol: Privet pollen and food extracts of White Potato, Corn, Oat, Rye, and Wheat. Injections of such extracts discolored by reaction with phenol may produce a lasting tattoo-like discoloration of the skin.

2. Information for Patients

Patients should be instructed in the recognition of adverse reactions to immunotherapy, and in

particular, to the symptoms of shock. (See WARNINGS box at the beginning of this package insert.) Patients should be made to understand the importance of a 30 minute observation period, and be cautioned to return to the office promptly if symptoms occur after leaving. Patients should be instructed to report any symptoms of exposure to the allergen, so the physician can adjust the dosage appropriately.

3. Drug Interactions

Patients with cardiovascular diseases and/or pulmonary diseases such as symptomatic unstable, steroid-dependent asthma, and/or those 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 allergy treatment regimen. Patients should be treated only if the benefit of treatment outweighs the risks.1

Patients on 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.2 (See WARNINGS).

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. 28 Topical steroids should be discontinued at the skin test site for at least 2-3 weeks before skin testing.28, 29

Tricyclic antidepressants such as Doxepin should be withheld for at least 7 days before skin testing. 30

Topical local anesthetics may suppress the flare responses and should be avoided in skin test sites.31

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

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. Allergenic extracts should be given to a pregnant woman only if clearly needed. The physician must carefully consider the benefit-to-risk ratio to both patient and fetus, of performing skin testing or continuing immunotherapy during pregnancy. The recommended precautions (See WARNINGS AND PRECAUTIONS) for preventing adverse reactions are especially important in the pregnant patient. Based on the physician's discretion, immunotherapy maintenance doses may be continued during pregnancy if the patient has not experienced adverse side effects. Immunotherapy is generally not initiated during pregnancy due to the risks associated with systemic reactions and their treatment. 33

6. Nursing Mothers

There are no current studies on the secretion of allergenic extract components in human milk or their 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

Since dosage for the pediatric population is the same as for adults 34, 35 larger volumes of solution may produce excessive discomfort. Therefore, in order to achieve the total dose required, the volume of the dose may need to be divided into more than one injection per visit.

8. Geriatric Use

The reactions from immunotherapy can be expected to be the same in elderly patients as in younger ones. Elderly patients may be more likely to be on medication that could block the effect of epinephrine

which could be used to treat serious reactions, or they could be more sensitive to the cardiovascular side effect of epinephrine because of pre-existing cardiovascular disease. 36

ADVERSE REACTIONS

Physicians administering allergenic extract testing or treatment materials should be experienced in the treatment of severe systemic reactions. See WARNINGS box at the beginning of this package insert.

1. Local Reactions

Some erythema, swelling or pruritus at the site of injection are common, the extent varying with the patient. Such reactions should not be considered significant unless they persist for at least 24 hours. Local reactions (erythema or swelling) which exceed 4-5 cm in diameter are not only uncomfortable, but also indicate the possibility of a systemic reaction if dosage is increased. In such cases the dosage should be reduced to the last level not causing the reaction and maintained at this level for two or three treatments before cautiously increasing again. Large persistent local reactions may be treated by local cold, wet dressings and/or the use of oral antihistamines. They should be considered a warning of possible severe systemic reactions and an indication of the need for temporarily reduced dosages. A mild burning immediately after the injection is to be expected. This usually subsides in 10 to 20 seconds.

2. Systemic Reactions

With careful attention to dosage and administration, systemic reactions occur infrequently, but it cannot be overemphasized that in sensitive individuals, any injection could result in anaphylactic shock. Therefore, it is imperative that physicians administering allergenic extracts understand and be prepared for the treatment of severe reactions.

Most severe systemic reactions will begin within a 30 minute time period, but systemic reactions may occur at any time after skin tests or immunotherapy. Symptoms may range from mild to life-threatening (due to anaphylaxis)as described below.

Other possible systemic reactions which may occur in varying degrees of severity are laryngeal edema, fainting, pallor, bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis, and urticaria. Adverse reaction frequency data for allergenic extract administration for testing and treatment show that risk is low. 1, 37

If a systemic or anaphylactic reaction does occur, apply a tourniquet above the site of injection and inject 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 DOSAGE:

ADULT: 0.3 to 0.5 mL should be injected. Repeat in 5 to 10 minutes if necessary.

PEDIATRIC: 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 possibly vasoactive drugs. Airway patency should be insured. Oxygen should be given by mask. Intravenous antihistamine, inhaled bronchodilators, theophylline and/or adrenal corticosteroids may be used if necessary after adequate epinephrine and circulatory support has been given. Emergency resuscitation measures and personnel trained in their use must be available immediately in the event of a serious systemic or anaphylactic reaction not responsive to the above measures [*Ref. J. Allergy and Clinical Immunology*, 77(2):p. 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.

Severe systemic reactions mandate a decrease of at least 50% in the next dose, followed by cautious

increases. Repeated systemic reactions, even of a mild nature, are sufficient reason for the cessation of further attempts to increase the reaction-causing dose.

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.

OVERDOSE SECTION

See ADVERSE REACTIONS.

DOSAGE AND ADMINISTRATION

1. General

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

Dosage of allergenic extracts is a highly individualized matter and varies according to the degree of sensitivity of the patient, his clinical response, and tolerance to the extract administered during the early phases of an injection regimen.

Allergen extracts should be administered using a sterile syringe with 0.01 mL gradations and a 25-27 gauge x 1/2" to 5/8" needle. The injections are given subcutaneously. The most common sites of injection are the lateral aspect of the upper arm or thigh. Intracutaneous or intramuscular injections may produce large local reactions and may be very painful.

Sterile aqueous diluent containing human serum albumin [Albumin Saline with Phenol (0.4%)] or diluent of 50% glycerin may be used when preparing dilutions of the concentrate for immunotherapy. Dilutions should be made accurately and aseptically, using sterile diluent, vials, syringes, etc. Mix thoroughly and gently by rocking or swirling. Maintain stock solutions and dilutions constantly at 2° - 8°C. To prepare dilutions for intradermal and therapeutic use, make a 1:10 dilution by adding 1.0 mL of the Concentrate to 9.0 mL of sterile aqueous diluent. Subsequent serial dilutions are made in a similar manner.

Following is a suggested schedule for average patients and will be satisfactory in most cases. However, the degree of sensitivity varies in many patients. The size of the dose should be adjusted according to the patient's tolerance and reaction. Decrease the size of the dose if the previous injection resulted in marked local or the slightest general reaction. Another dose should never be given until all reactions resulting from the previous dose have disappeared.

The starting dose should be based on skin tests of the extract to be used for immunotherapy. To determine the starting dose, begin intradermal testing with the most dilute extract preparation. Inject 0.02 mL and read the reaction after 15 minutes. Intradermal testing is continued with increasing concentrations of the extract until a reaction of 10-20 mm erythema ($\sum$ E 0-40 mm) and/or a 5 mm wheal occurs. This concentration at a dose of 0.03 mL then can serve as a starting dose for immunotherapy. Subsequent doses can be increased by 0.03 mL to as high as 0.12 mL increments each time until 0.3 mL is reached, at which time a dilution 10 times as strong can be used, starting with 0.03 mL. Proceed in this way until a tolerance dose is reached or symptoms are controlled. Suggested maintenance dose for a pollen extract is 0.2 mL of the Concentrate, while for a non-pollen extract the maximum suggested dose is 0.5 mL of the Concentrate. Occasionally, higher doses are necessary to relieve symptoms. Special caution is required in administering doses greater than 0.2 mL. The interval between doses is normally 3 to 7 days during dose building regimen.

Normally immunotherapy can be started with a 1:100,000 dilution of extracts labeled in weight/volume. Certain therapeutic mixtures are labeled as Concentrate, (v/v) dilutions of Concentrate, Amb a 1, Allergy

units/mL or Bioequivalent Allergy Units/mL. (See DESCRIPTION.) Strength of each antigen in the mixture is indicated in the product labeling. For beginning treatment, use at least a 1,000-fold dilution of the Concentrate extract for non-pollens, and at least a 10,000-fold dilution of the Concentrate extract for pollens.

In some patients, the dosage may be increased more rapidly than recommended above. In seasonal allergies, treatment should be started and the interval between doses regulated so that at least the first twenty doses will have been administered by the time symptoms are expected. Thus, the shorter the interval between the start of immunotherapy and the expected onset of symptoms, the shorter the interval between each dose. Some patients may even tolerate daily doses.

Should symptoms develop before the next injection is scheduled, the interval between doses should be decreased. Should allergic symptoms or local reactions develop shortly after the dose is administered, the size of the dose should be decreased. In seasonal allergies, it is often advisable to decrease the dose to one-half or one-quarter of the maximum dose previously attained if the patient has any seasonal symptoms.

A maintenance dose, the largest dose tolerated by the patient that relieves symptoms without producing undesirable local or general reactions, is recommended for most patients. The upper limits of dosage have not been established; however, doses larger than 0.2 mL of extract may be painful if glycerin is present. The dosage of allergenic extract does not vary significantly with the respiratory allergic disease under treatment. The size of this dose and the interval between doses will vary and can be adjusted as necessary.

The interval between maintenance doses can be increased gradually from one week to 10 days, to two weeks, to three weeks, or even to four weeks, if tolerated. Repeat the doses at a given interval three or four times to check for untoward reactions before further increasing the interval. Protection is lost rapidly if the interval between doses is more than four weeks. (See WARNINGS.)

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

2. Pediatric Use

The dose for the pediatric population is the same as for adults.

3. Geriatric Use

The dose for elderly patients is the same as for adult patients under 65.36

HOW SUPPLIED

In 10 mL, 30 mL and 50 mL vials at the w/v, Concentrate, v/v dilution of Concentrate, AU/mL (Standardized Mite Extracts: D. farinae, D. pteronyssinus 10,000 and 30,000 AU/mL; Mite Mixtures: 5,000 AU/mL each species, or 15,000 AU/mL each species), BAU/mL (Standardized Cat Hair and Cat Pelt extracts: 10,000 BAU/mL; Standardized Grass extracts: 10,000 and 100,000 BAU/mL); Amb a 1 units/mL; or PNU/mL ordered by the physician. Please see the current Allergy Product Catalog.

STORAGE AND HANDLING

The expiration date is listed on the container label. To ensure the maximum potency, the extract and its dilutions should be stored at 2° - 8°C, and kept in this temperature range at all times, even during use. Dilutions are less stable than concentrates. If loss of potency is suspected, dilutions should be checked by skin testing with equal v/v dilutions of a freshly prepared dilution on individuals known to be allergic to the specific allergen.

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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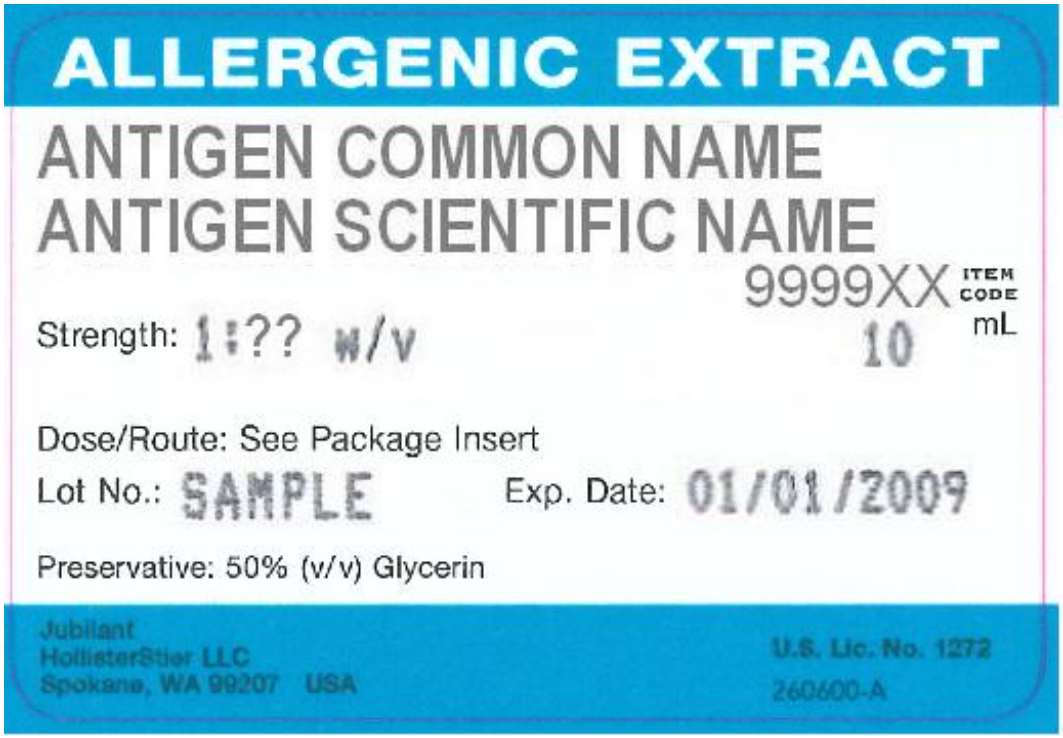

POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS

sagebrush, mugwort artemisia vulgaris injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-2413
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D)	ARTEMISIA VULGARIS POLLEN	0.05 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:65044-2413-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2413-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2413-4	50 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	

POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS

sagebrush, mugwort artemisia vulgaris injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-2416
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D)	ARTEMISIA VULGARIS POLLEN	0.1 g in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2416-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2416-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2416-4	50 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	

POLLENS - WEEDS AND GARDEN PLANTS, SAGEBRUSH, MUGWORT ARTEMISIA VULGARIS

sagebrush, mugwort artemisia vulgaris injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-2417
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARTEMISIA VULGARIS POLLEN (UNII: ANT994T71D) (ARTEMISIA VULGARIS POLLEN - UNII:ANT994T71D)	ARTEMISIA VULGARIS POLLEN	40000 [PNU] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2417-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2417-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2417-4	50 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	

POLLENS - WEEDS AND GARDEN PLANTS, SCALE, WING SHAD ATRIPLEX CANESCENS

scale, wing shad atriplex canescens injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	Item Code (Source)	NDC:65044-2482
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATRIPLEX CANESCENS POLLEN (UNII: 26U0BU8G83) (ATRIPLEX CANESCENS POLLEN - UNII:26U0BU8G83)	ATRIPLEX CANESCENS POLLEN	0.05 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:65044-2482-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2482-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2482-4	50 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	

POLLENS - WEEDS AND GARDEN PLANTS, SCALE, WING SHAD ATRIPLEX CANESCENS

scale, wing shad atriplex canescens injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-2485
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATRIPLEX CANESCENS POLLEN (UNII: 26U0BU8G83) (ATRIPLEX CANESCENS POLLEN - UNII:26U0BU8G83)	ATRIPLEX CANESCENS POLLEN	0.1 g in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2485-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2485-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2485-4	50 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	

POLLENS - WEEDS AND GARDEN PLANTS, SCOTCH BROOM CYTISUS SCOPARIUS

scotch broom cytisus scoparius injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-2487
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYTISUS SCOPARIUS FLOWERING TOP (UNII: XZC6H8R666) (CYTISUS SCOPARIUS FLOWERING TOP - UNII:XZC6H8R666)	CYTISUS SCOPARIUS FLOWERING TOP	0.05 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:65044-2487-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2487-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2487-4	50 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	

POLLENS - WEEDS AND GARDEN PLANTS, SORREL, SHEEP RUMEX ACETOSELLA

sorrel, sheep rumex acetosella injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-2506

Route of Administration	PERCUTANEOUS, SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW)	RUMEX ACETOSELLA POLLEN	0.05 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:65044-2506-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2506-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2506-4	50 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	

POLLENS - WEEDS AND GARDEN PLANTS, SORREL, SHEEP RUMEX ACETOSELLA

sorrel, sheep rumex acetosella injection, solution

Product Information

Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-2508
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW)	RUMEX ACETOSELLA POLLEN	0.1 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-2508-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2508-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2508-4	50 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	

POLLENS - WEEDS, CARELESS WEED AMARANTHUS PALMERI

careless weed amaranthus palmeri injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-1297
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AMARANTHUS PALMERI POLLEN (UNII: 1GH3WV23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3WV23KH)	AMARANTHUS PALMERI POLLEN	0.05 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:65044-1297-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-1297-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-1297-4	50 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	

POLLENS - WEEDS, CARELESS/PIGWEED MIX

careless/pigweed mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-1300
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMARANTHUS PALMERI POLLEN (UNII: 1GH3WV23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3WV23KH)	AMARANTHUS PALMERI POLLEN	0.05 g in 1 mL
AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW)	AMARANTHUS RETROFLEXUS POLLEN	0.05 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:65044-1300-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-1300-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-1300-4	50 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	

POLLENS - WEEDS, CARELESS/PIGWEED MIX

careless/pigweed mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-1303
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMARANTHUS PALMERI POLLEN (UNII: 1GH3WV23KH) (AMARANTHUS PALMERI POLLEN - UNII:1GH3WV23KH)	AMARANTHUS PALMERI POLLEN	0.1 g in 1 mL
AMARANTHUS RETROFLEXUS POLLEN (UNII: 73B14PX5FW) (AMARANTHUS RETROFLEXUS POLLEN - UNII:73B14PX5FW)	AMARANTHUS RETROFLEXUS POLLEN	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65044-1303-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-1303-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-1303-4	50 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	

POLLENS - WEEDS, DOCK/SORREL MIX

pollens - weeds, dock/sorrel mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-1516
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G)	RUMEX CRISPUS POLLEN	0.05 g in 1 mL
RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW)	RUMEX ACETOSELLA POLLEN	0.05 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:65044-1516-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-1516-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-1516-4	50 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	

POLLENS - WEEDS, DOCK/SORREL MIX

pollens - weeds, dock/sorrel mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-1519
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G)	RUMEX CRISPUS POLLEN	0.1 g in 1 mL
RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW)	RUMEX ACETOSELLA POLLEN	0.1 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65044-1519-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-1519-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-1519-4	50 mL in 1 VIAL; Type 0: Not a Combination Product		

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POLLENS - WEEDS, DOCK/SORREL MIX

pollens - weeds, dock/sorrel mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-1520
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RUMEX CRISPUS POLLEN (UNII: V825XJG64G) (RUMEX CRISPUS POLLEN - UNII:V825XJG64G)	RUMEX CRISPUS POLLEN	20000 [PNU] in 1 mL
RUMEX ACETOSELLA POLLEN (UNII: N52MIQ81ZW) (RUMEX ACETOSELLA POLLEN - UNII:N52MIQ81ZW)	RUMEX ACETOSELLA POLLEN	20000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOL (UNII: 339NCG44TV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65044-1520-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-1520-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-1520-4	50 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	

POLLENS - WEEDS, GIANT, SHORT, WESTERN RAGWEED MIX

giant, short, western ragweed mix injection, solution

Product Information			
Product Type	NON-STANDARDIZED ALLERGENIC	**Item Code (Source)**	NDC:65044-2320
Route of Administration	PERCUTANEOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMBROSIA TRIFIDA POLLEN (UNII: KU1V1898XX) (AMBROSIA TRIFIDA POLLEN - UNII:KU1V1898XX)	AMBROSIA TRIFIDA POLLEN	0.05 g in 1 mL
AMBROSIA ARTEMISIIFOLIA POLLEN (UNII: K20Y81ACO3) (AMBROSIA ARTEMISIIFOLIA POLLEN - UNII:K20Y81ACO3)	AMBROSIA ARTEMISIIFOLIA POLLEN	0.05 g in 1 mL
AMBROSIA PSILOSTACHYA POLLEN (UNII: RX18M46K8L) (AMBROSIA PSILOSTACHYA POLLEN - UNII:RX18M46K8L)	AMBROSIA PSILOSTACHYA POLLEN	0.05 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:65044-2320-2	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:65044-2320-3	30 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:65044-2320-4	50 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

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BLA	BLA103888	04/19/1941	

Labeler - Jubilant HollisterStier LLC (069263643)

Registrant - Jubilant HollisterStier LLC (069263643)

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