STANDARDIZED CAT PELT

INDICATIONS AND USAGE:

1. Bioequivalent Allergy Units. When originally licensed, standardized cat extracts containing 10 – 20 Fel d 1 units/mL were arbitrarily assigned 100,000 Allergy Units (AU/mL). Subsequently, quantitative skin testing by the IDEAL method was used to determine that standardized cat extracts containing 10 – 19.9 Fel d 1 units/mL should be assigned 10,000 AU/mL rather than 100,000 AU/mL. To avoid possible confusion about this change in allergy unit assignment, the nomenclature changed for cat extracts, and such products are labeled in Bioequivalent Allergy Units (BAU/mL). Each lot of Standardized Cat Pelt extract is standardized by quantifying the Fel d 1 content based on standards on file with the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration. Test extracts are diffused in agar and compared to a reference allergy preparation. The potency of the extract is expressed as units of Fel d 1 per mL, and extracts containing 10–19.9 Fel d 1 units/mL are labeled at 10,000 BAU/mL. It has been recognized that there are differences in the levels of non Fel d 1 allergens among standardized cat extracts which utilize different source materials. Isoelectric focusing (IEF) patterns have been shown to be predictive of the presence of non Fel d 1 allergens. Therefore, each lot of Standardized Cat Pelt is compared by IEF to a Cat Pelt Extract Reference and a Cat Hair Extract Reference on file with the CBER. The labeled name of the cat extract (i.e., Cat Hair Extract or Cat Pelt Extract) must be supported by matching the IEF profile of the corresponding reference.

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

<table>
<thead>
<tr>
<th>Concentrate</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Rayp 1:29 w/v</td>
<td>10,000 BAU/mL</td>
</tr>
<tr>
<td>Std. Cat. Pelt 10,000 BAU/mL</td>
<td>25%</td>
</tr>
<tr>
<td>Std. Mite D. farinae 10,000 AU/mL</td>
<td>25%</td>
</tr>
</tbody>
</table>

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 = Allergen Manufacturing Strength x % Allergen in Formulation

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Bioequivalent Allergy Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active ingredients</td>
<td>50% (v/v) as a preservative. Glycerinated extracts contain 0.5% sodium chloride, 0.275% sodium bicarbonate and 50% glycerin (v/v) as a preservative.</td>
</tr>
</tbody>
</table>

WARNINGs:

1. 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. Allergic extracts may potentially elicit a severe life-threatening systemic reaction, rarely resulting in death. Therefore, emergency measures and personnel trained in their use must be readily available in the event of such a reaction. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician’s office if symptoms occur.

2. This standardized extract may be more potent than regular extracts and therefore is not directly interchangeable with our non-standardized extracts, or other manufacturers’ products. Standardized pelts and hair extracts are manufactured from different source materials and are not interchangeable. Standardized cat extracts labeled in AU/mL are not interchangeable with extracts labeled in BAU/mL. See DESCRIPTION Section.

3. This product should never be injected intravenously.

4. Patients on non-selective beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. 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 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

5. The histamine release response of circulating basophils to a specific allergen is reduced in some patients who are receiving cardiovascular drugs such as beta blockers, and therefore is reduced in some patients who are receiving cardiovascular drugs such as beta blockers, and therefore may occur to the highly reactive allergen.

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

7. To avoid 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 one of the needed allergens.

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

9. 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 to the highly reactive allergen.

10. ARTIFICIAL INSEMINATION: There are no known absolute contraindications to immunotherapy. See PRECAUTIONS for pregnancy risks.

11. Patients with cardiovascular diseases or pulmonary diseases such as symptomatic 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 reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. 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

12. The relationships among changes in blocking antibody, reaginic antibody, and mediator-releasing cells, and the relationship of changes in reaginic antibody and blocking antibody to 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).

13. The mechanisms by which hyposensitization is achieved are not completely understood. It has been shown that repeated injections of appropriate allergenic extracts increase the number of 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 who are receiving cardiovascular drugs such as beta blockers, and therefore may occur to the highly reactive allergen.

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

15. 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 to the highly reactive allergen.

16. To avoid 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 one of the needed allergens.

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

18. 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 to the highly reactive allergen.

19. To avoid 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 one of the needed allergens.

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

21. 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 to the highly reactive allergen.

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

23. WARNINGS: See WARNINGS at the beginning of this instruction sheet.

Allergic extract should 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...
by fever; or (3) exposure to excessive amounts of clinically relevant allergen prior to a scheduled injection. Do not start 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 concentration should not be injected at any time unless tolerance has been established. Dilute concentrated extracts with sterile diluent for intradermal testing. Injections should never be given intravenously. Subcutaneous injection is recommended. Intracutaneous or intramuscular injection may produce large local reactions or be excessively painful.

Intradermal injection should be given only by a trained health care provider. The injection of the antigen should be superficial, with minimal trauma to the skin. Injection sites should be cleaned to avoid bacterial contamination. The concentration should not be injected at any time unless tolerance has been established. It must be proven that the patient has not developed tolerance to varying dilutions of the extract. See PRECAUTIONS and DOSAGE AND ADMINISTRATION Sections.

If changing from a non-allergen to an allergen, the dose must be increased to induce a response. If changing from an allergen to a non-allergen, the dose must be decreased to prevent an adverse reaction. It is important to know the amount of extract required to produce a local reaction of varying size.

If changing from hair to pelts, the extract concentration used in hair extracts should be used in pelts.

Proper selection of the dose and careful injection should prevent most systemic reactions. It must be remembered, however, that allergic reactions 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, tarry, ear pain, fainting, or even anaphylactic shock and death. Patients should be informed of this, and the precautions should be discussed prior to immunotherapy. (See PRECAUTIONS below.) Severe systemic reactions should be treated as indicated in the ADVERSE REACTIONS Section. Refer to boxed WARNING Section.

Precautions:

1. General

Concentrated extracts must be diluted prior to use. See DOSAGE AND ADMINISTRATION Section below 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 diluent containing 0.4% Phenol may be more potent than extracts diluted with diluents which do not contain stabilizers. When changing from non-stabilized to stabilized diluent, consider weaker initial dilutions for both intradermal 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 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 serum hepatitis and other infectious agents from one person to another.

Patient reactions to previous injections should be reviewed before each new injection. A conservative dosage schedule should be followed by the physician until a pattern of local responses is established which can be used to monitor increases in dosage.

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 discontinued.

Patients should be observed in the office for 30 minutes after each treatment injection. Most severe reactions will occur within this time period, and rapid treatment measures should be instituted. See ADVERSE REACTIONS Section for such treatment measures.

2. Information for Patients

Patients should be instructed in the recognition of adverse reactions to immunotherapy, and in particular, to the symptoms of shock. Patients should be made to understand the importance of a 30 minute observation period, and be warned to return to the office promptly if symptoms occur after leaving.

3. Drug Interactions

Patients on non-selective beta blockers may be more reactive to allergens given for testing and treatment than patients given beta blockers specific to the usual doses of epinephrine used to treat allergic reactions. 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 1 weeks prior to skin tests.25 Topical steroids should be discontinued at the skin test site for at least 2-3 weeks before skin testing.24, 25 Topical local anesthetics may suppress the flare responses and should be avoided in skin test sites.24

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

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

6. Nursing Mothers

There are no current studies on secretion of the allergenic extract components in human milk or effect on the nursing infant. Because many drugs are excreted in human milk, caution should be exercised when allergenic extracts are administered to a nursing woman.
7. Pediatric Use
Since dosage for the pediatric population is the same as for adults1-4, the 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.20

ADVERSE REACTIONS:

1. Local Reactions
Some erythema, swelling or pruritus at the site of injection are common, the extent varying with the patch test concentration. The reactions should not be consideread 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 or treatment initiated last 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 anti- histamines. 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 leaves 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.

Other possible systemic reactions which may occur in varying degrees of severity are laryngeal edema, faintness or bradycardia, hypotension, angioedema, cough, wheezing, conjunctivitis, rhinitis, and urticaria. Adverse reaction frequency data for allergenic extract administration for testing and treatment after adequate epinephrine and circulatory support has been given.

Therefore, it is imperative that physicians administering allergenic extracts understand and be prepared in advance for all contingencies. Promptness in administration whenever solution and container permit.

Emergency resuscitation measures and personnel trained in their use should be available immediately 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, theophylline and/or corticosteroids may be used if necessary after adequate epinephrine and circulatory support has been given. Adverse reaction frequency data for allergenic extract administration for testing and treatment show that risk is low.21

If a systemic or anaphylactic reaction occurs, inject a tourniquet above the site of injection and inject 1:1000 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.

EPIINEPHRINE 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 dosages 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, theophylline and/or corticosteroids may be used if necessary after adequate epinephrine and circulatory support has been given. Emergency resuscitation measures and personnel trained in their use should be available immediately in the event of a serious systemic or anaphylactic reaction 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) 902-1120. 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 (1800) FDA-1088. Completed forms should be mailed to MEDWATCH, 5600 Fisher Lane, Rockville, MD 20852-9767 or Fax to 1 (800) FDA-0178.

OVERDOSAGE: See ADVERSE REACTIONS Section.

DOSEAGE AND ADMINISTRATION: 1, 16, 17, 18

1. General
Sterile aqueous diluent containing human serum albumin is recommended when preparing dilutions of the concentrate for intradermal testing or immunotherapy. Dilutions should be made accurately and aseptically, using sterile diluent, vials, syringes, etc. Mix thoroughly and gently by rocking or swirling.

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

2. Diagnosis
To identify highly sensitive individuals and as a safety precaution, it is recommended that a prick or puncture test using a drop of the extract concentrate be performed prior to initiating intradermal testing. Prick tests are performed by placing a drop of extract on the skin and piercing through the drop perpendicularly to the skin with a device such as a Prick Lancetter. After about 1 minute, the extract may be wiped away with a dry sponge. The diameter of the wheal and erythema reactions are measured 15 minutes after the prick or puncture is made, and the sensitivity class of the patient determined by the table presented at the end of the diagnosis section. Less sensitive individuals (Class 0 to 1+) can be tested intradermally with the recommended dilutions of the extract concentrate (see Intradermal Testing).

The skin test concentration of 10.000 BAU/mL (10-19.9 Fel 1 Units/mL) in dropper vials is used for prick or puncture testing. Puncture tests performed on 15 highly sensitive subjects showed the following:

<table>
<thead>
<tr>
<th>Product</th>
<th>Mean Sum of Wheal</th>
<th>Mean Sum of Erythema</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardized Cat Pelt</td>
<td>13.9 ± 4.3</td>
<td>67.3 ± 13.3</td>
</tr>
</tbody>
</table>

The sum of a skin response is the sum of the longest diameter and the mid-point orthogonal diameter. Intradermal endpoint titration (ET) tests were completed using the same 15 subjects to determine the mean concentration required to produce a ΔΣ of 50mm (Dis). That concentration contained 0.042 BAU/mL, (range 0.002 to 0.800 BAU/mL).

Intradermal extract should be used as follows:

Intradermal Tests should be done only on patients with a negative prick or puncture test. Patients who do not react to a valid prick or puncture test should be tested intradermally with 0.02 to 0.05 mL of a 100 BAU/mL extract solution. If this test is negative, a second intradermal test may be performed using a 1,000 BAU/mL extract solution. If the intradermal dilutions were prepared from glycerinated concentrate, the negative control used with this latter dilution should contain 5% glycerol.

Skin tests are graded in terms of the wheal and erythema size. The diameter of the wheal and erythema size is measured by actual measurement of the extent of both responses.

Referring to the following table to determine the skin test sensitivity class. The corresponding ΔΣ (sum of the longest diameter and the mid-point orthogonal diameters of erythema) is also presented.

<table>
<thead>
<tr>
<th>Class</th>
<th>Wheal Diameter</th>
<th>Erythema Diameter</th>
<th>Corresponding ΔΣ</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>&lt;5 mm</td>
<td>&lt;5 mm</td>
<td>&lt;10 mm</td>
</tr>
<tr>
<td>1</td>
<td>5-10 mm</td>
<td>5-10 mm</td>
<td>10-20 mm</td>
</tr>
<tr>
<td>2</td>
<td>5-10 mm</td>
<td>11-20 mm</td>
<td>20-40 mm</td>
</tr>
<tr>
<td>3</td>
<td>5-10 mm</td>
<td>21-30 mm</td>
<td>40-60 mm</td>
</tr>
<tr>
<td>4</td>
<td>5-10 mm</td>
<td>31-40 mm</td>
<td>&gt;40 mm</td>
</tr>
<tr>
<td>5</td>
<td>&gt;15 mm</td>
<td>&gt;40 mm</td>
<td>&gt;80 mm</td>
</tr>
</tbody>
</table>

a. or with pseudopsod b. with many pseudopsod

3. Immunotherapy
Allergic extracts should be administered using a sterile syringe with 0.01 mL gradients 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 which may be very painful.

Dosage of allergic extracts is a highly individualized matter and varies according to the degree of sensitivity of the patient, his clinical response, and tolerance to the extract administered during the early phases of an injection regimen. The starting dose should be based on skin tests of the extract to be used for immunotherapy. 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 may be made in a similar manner. (See Table I.) To determine the starting dose, begin intradermal testing with the most
Storage:
The expiration date of the Standardized Cat Pelt extract containing 10,000 BAU/mL is listed on the container label. The extract should be stored at 2° - 8°C. Dilutions of the BAU/mL concentrates are less stable and, if loss of potency is suspected, should be checked by skin testing with equal bioequivalent allergy units of a freshly prepared dilution on known cat allergic individuals.

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, 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 label or packaging the product, except by printed notice from the Company’s headquarters. The prescriber and user must accept the terms and conditions hereof.

References: