

HOW SUPPLIED:

Therapeutic allergenic extracts are supplied in 12 ml or 30 ml multiple dose vials as individual allergens or mixtures prescribed by the veterinarian. Allergenic extracts are sold according to Weight/Volume (w/v) and Protein Nitrogen Unit/ml. (PNU/ml)

STORAGE

Refrigeration at 2°C to 8°C and no higher than 46°F (8°C) recommended. DO NOT FREEZE.

SPECIAL PRECAUTIONS:

In the unlikely event that a human might receive a dose of this product, immediately consult a physician experienced in allergic reactions. If a severe allergic reaction occurs (i.e.: shock, anaphylaxis, dyspnea) administer oral antihistamines or intramuscular epinephrine and go to an emergency center.

WARRANTY:

We warrant that this product was prepared and tested according to the standards of the USDA and is true to label.

References

1. *Allergic Skin Diseases of Dogs and Cats*, L.M. Reedy, W.H. Miller, Jr., W.B. Saunders Company, Philadelphia, 1989.
2. *Small Animal Dermatology, 4th edition*, G.H. Muller, R.W. Kirk, D.W. Scott, W.B. Saunders Company, Philadelphia, 1989.
3. *Small Animal Allergy*, Edward Baker, Lea and Febinger, Philadelphia, 1990.
4. *Veterinary Clinical Immunology*, R.E. W. Halliwell and Neil Gorman, W.B. Saunders Company, Philadelphia, 1989.
5. *Advances in Veterinary Dermatology, Volume 2*, P.J. Ihrke, I.S. Mason, S.D. White, Pergamon Press, New York, 1992.
6. *Small Animal Dermatology, 5th edition*, D.W. Scott, W.H. Miller, Jr., C.E. Griffin, W.B. Saunders Co., Philadelphia, 1995.
7. *Veterinary Dermatology*, D.J. DeBoer, M. Verbrugge, and M. Morris. Vol. 21, Pg 325; Pilot trial of sublingual immunotherapy (SLIT) in mite-sensitive atopic dogs, 2010.
8. *Clinical Immunology and Allergy*, G. B. Gidaro, F. Marcucci L. Sensi, C. Incorvaia, F. Frati and G. Ciprandi. The safety of sublingual-swallow immunotherapy: an analysis of published studies Vol. 5, Pgs 565-571. 2005.

Manufactured by:

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**ALLERGENIC EXTRACT
FOR SUBLINGUAL IMMUNOTHERAPY (SLIT)
FOR VETERINARY USE IN THE TREATMENT
OF ATOPIC ALLERGY**

**DIRECTIONS FOR USE
and
SUGGESTED DOSAGE SCHEDULE**

**MANUFACTURED
by
NELCO VET, LLC
154 BROOK AVENUE
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U.S. VETERINARY LICENSE No. 359

DESCRIPTION:

Extracts are prepared with one of four extracting solutions: 1) Buffered diluent containing NaCl 0.5%, KH₂PO₄ 0.036%, Na₂HPO₄ 0.08%, sterile water for injection, 0.4% phenol as a bacteriostatic agent; 2) Coca's fluid containing 0.5% NaCl, 0.275% NaHCO₃, 0.4% phenol and sterile water for injection; 3) 0.5% saline containing 0.4% phenol and sterile water for injection; or 4) 0.9% saline containing 0.4% phenol and sterile water for injection. All extracts for oral allergy treatment are prepared with diluent plus 50% glycerin as a preservative.

POLLENS:

Animals are exposed to pollens any time they are outside and in contact with pollen releasing plants. Pollen levels depend on the number of plants in the area and the efficiency of pollen release. Dry, defatted pollens of various grasses, trees, and weeds are extracted and prepared in Coca's solution.

MOLDS, FUNGI:

Fungi are universal in distribution, are common indoors and outdoors and frequently a major cause animal allergies when they become airborne. Mold sensitive animals experience allergic symptoms from the time the snow melts in the spring until the first substantial snowfall of the winter. Fungal antigens are extracts of spores of pure cultured molds. Fungal extracts are prepared from lyophilized cultures extracted in synthetic mold medium.

HOUSE DUST:

House dust allergy is a common cause of allergy in animals because of its heterogeneous composition. House dust is extracted in Coca's solution.

MITES:

Dermatophagoides farinae and *Dermatophagoides pteronyssinus* are common house dust mites and are grown in a medium consisting of yeast and pork products. Products of human origin are not used in the growth medium.

EPIDERMALS:

Defatted material is obtained from natural dander or hair sources.

INSECTS:

Extracts are made from the whole bodies of insects grown in laboratory colonies. Allergenic insect extracts, particularly stinging insects, should be administered with caution.

HUMAN HAIR:

Caution: Allergenic extracts of human hair contains a human source component. No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore, all human source material should be considered potentially infectious to humans, and it is recommended that this product be handled in accordance with appropriate biosafety practices and administered therapeutically only if diagnostic testing indicates an allergic response to human hair.

CLINICAL PHARMACOLOGY

The pharmacological action of allergenic extracts used diagnostically is based on the liberation of histamine and other substances when the allergen reacts with IgE antibodies attached to the mast cells. Allergens interact with Immunoglobulin E to stimulate the release of mediators such as histamine from the surface of mast cells and cause skin induration and erythema. Diagnostic skin testing is useful to confirm the diagnosis of atopy. When allergen extracts are used for therapeutic immunotherapy, the effect is an increase in Immunoglobulin G (IgG) and increased T suppresser lymphocyte which interferes with the allergic response. Although immunotherapy may be considered as immuno-suppression, in which the production of allergen-specific antibody is inhibited, the mechanism of the clinical effectiveness of immunotherapy is not completely understood.

INDICATIONS AND USAGE

Diagnosis: Allergy skin testing or *in-vitro* allergy testing is used to confirm a diagnosis of atopic disease and to identify offending allergens. Once the allergens are identified, specific therapies of avoidance, immunotherapy, and symptomatic therapy can be initiated.

Treatment - Hyposensitization: Results of specific diagnostic test indicating a positive reaction to selected allergens are necessary prior to initiating hyposensitization (immunotherapy) treatment. The goal of immunotherapy is to increase the animal's ability to tolerate exposure to certain allergens without developing clinical signs. Immunotherapy attempts to normalize the underlying immunologic defect and minimize the animal's hyper-reactivity.

Sublingual immunotherapy (SLIT) is based on the same principles of desensitization as subcutaneous immunotherapy (SCIT). With SLIT, a measured amount of allergenic extract is sprayed under the animals tongue rather than being injected under the animal's skin (SCIT).

CONTRAINDICATIONS

Allergenic extracts are not recommended for immunotherapy use unless specific allergen hypersensitivity has been identified by means of *in vivo* or *in vitro* testing.

WARNING and PRECAUTIONS:

FOR USE IN DOGS AND CATS ONLY

General Information

- DO NOT INJECT THIS MATERIAL INTO THE ANIMAL.**
- To aid absorption of allergenic extract, the animal should be kept from food or drink for 30 minutes before and after receiving a dose.
- In case of a sudden, serious reaction, the following drugs should be readily available for use by personnel experienced in their administration: Epinephrine 1:1000; Injectable antihistamine such as Diphenhydramine. Injectable fast-acting corticosteroid such as Hydrocortisone, Cortisone, Prednisone. Antihistamines: Hydroxyzine, Diphenhydramine, Chlorpheniramine.
- Therapy should be started with the *Starter Vial*, which is the weaker solution.
- Oral allergy treatment is given by dispensing the allergenic extract under the animals tongue.
- Animals should be observed for untoward reactions for 30 minutes after receiving a dose.

ADVERSE REACTIONS

Adverse reactions to allergenic extracts may occur during the initial build-up phase of immunotherapy. Adverse reactions may include increased pruritus, vomiting, diarrhea, personality changes, or weakness. Anaphylaxis, shock, and death are very rare and are usually preceded by other systemic reactions. Adverse reactions may require an adjustment to the dosage schedule to a dose that did not elicit a reaction.

OVERDOSAGE

See the section on ADVERSE REACTIONS for the signs and symptoms of overdose. In cases of a severe systemic reaction inject Epinephrine HCl 1:1000 intramuscularly. Subsequent treatment should proceed cautiously and with marked lowering of dosage so that an increase in dosage occurs more slowly and over a longer period of time.

SUGGESTED DOSAGE

Each animal's treatment schedule must be determined during a course of therapy by observing the degree of sensitivity the animal presents. The following schedules may be used as a guide. Very sensitive animals might have to begin with smaller doses of weaker solutions and the dosage increments might be less.

Treatment schedule

	DAY	DOSE
Build-up Phase	1	3 "squirts"
Use	to	per day or
Starter Vial	28	approximately
		0.3 ml per day
	DAY	DOSE*
Maintenance Phase	From day	3-8 "squirts"
Use	29	per day
Maintenance Vial	forward	
Note: Use Maintenance		six days
Vials one at a time		per week
until each is empty.		

- * The maintenance dose is a dose that stimulates positive changes in the animal's immune system but does not cause clinical signs or symptoms to recur. The maintenance dose may need adjustment depending on the animal's response.