Sublingual Immunotherapy
Initial Treatment
SLIT50

ACTT ALLERGY® DROPS

Specimen No:
Pet/Owner:
Services:
Serial No:
Expires:

Veterinarian

Vial Sequence: GREEN > BLUE > RED

Please read and follow all instructions detailed on both sides of this page.

Important - Allergy drops must be administered daily.

Vial	Week	Dose: 1 pump = 0.05 mL	Comments or Observations
GREEN VIAL Total duration Green vial - 2 weeks	**Week 1** **Week 2**	**Give 1 pump from Green vial, 1 time daily** **Give 1 pump from Green vial, 2 times daily**	Record beginning date:
BLUE VIAL Total duration Blue vial - 2 weeks	**Week 3** **Week 4**	**Give 1 pump from Blue vial, 1 time daily** **Give 1 pump from Blue vial, 2 times daily**	Record beginning date:
RED VIAL Total duration Red vial - 14 weeks * Week 14 - Contact your veterinarian to order refill treatment. *	**Week 5** **Week 6** **Week 7-18**	**Give 1 pump from Red vial, 1 time daily** **Give 1 pump from Red vial, 2 times daily** **Give 1 pump from Red vial, 3 times daily**	Record beginning date:

Warning: Allergy drops are intended for sublingual administration ONLY and are NOT INTENDED for injection.

Instructions for Administration:

1. No food or water 10 minutes before or after administration. Do not mix allergy drops with food or water.
2. If starting a new vial, attach pump to vial. Prime pump by depressing several times until a drop is released.
3. Prior to administering each dose, gently swirl the allergen solution. Do not invert.
4. Administer the drops under the pet's tongue, inside the cheek, or inside the lip. Follow the schedule described in the table above.
5. If you are uncertain if the drop was successfully placed under the pet's tongue, simply administer another drop.
6. Observe the animal for at least 30 minutes following each administration (see REACTIONS on back).
7. In the event of a severe reaction, discontinue drops and consult your veterinarian.
8. If scheduled doses are missed, do not try to "catch up"; simply resume treatment and follow the prescribed schedule as closely as possible.
9. Following administration, wipe the pump's nozzle to remove any allergens or saliva that may be on the surface.

Allergenic Extract, Prescription Product

Sublingual Immunotherapy

DESCRIPTION

Allergenic Extract Prescription Product Sublingual Immunotherapy is supplied as a solution containing soluble antigens extracted from source materials, preserved in a 50% glycerol solution.

Immunotherapy vials are labeled as weight-to-volume (Wt/Vol), based upon the weight of extracted antigen per volume of extracting fluid.

CLINICAL PHARMACOLOGY

Allergic reactions are dependent upon the presence of antigen-specific immunoglobulin E (IgE) antibodies bound to receptors on mast cells and basophils. Interaction of cell-bound IgE with specifically recognized allergen causes histamine and other inflammatory mediators to be released from these cells. IgE antibody has been shown to correlate with atopic diseases such as urticaria (hives), otitis (ear infection) and pruritus (itching).

Specific immunotherapy with Allergenic Extracts in a Sublingual immunotherapy vaccine formulation has been successfully employed to reduce symptoms associated with exposure to sensitizing allergens. Among the mechanisms thought to explain the effectiveness of immunotherapy are:

1) Sublingual administration of allergen extracts, at steadily increasing doses, induces higher serum levels of IgG in the patient. IgG preferentially binds to environmental allergens, thus limiting binding of allergen-IgE complexes to mast cells containing histamine.

2) Allergen specific immunotherapy induces changes in immunoregulatory proteins known as cytokines (Interleukins), which reduce allergy-favorable Th2 T cell responses and suppress IgE expression, thereby limiting the allergic response.

INDICATIONS AND USAGE

Allergenic Extract Prescription Product Sublingual Immunotherapy is indicated for treatment of patients with immediate hypersensitivity allergy to pollen, mold, dust mite, insect and other environmental allergens.

Diagnosis of IgE-mediated allergy is established after careful evaluation of the patient's clinical history and elimination of all other potential causes of the symptoms through differential diagnosis.

In vitro (serum IgE measurement) or in vivo (intradermal skin test) test methods are performed to identify sensitizing allergens for treatment.

Immunotherapy with Allergenic Extracts is indicated when testing and patient history have identified sensitizing allergens and when it is not possible or practical to avoid these allergens. Food extracts have not been proven effective in immunotherapy.

CONTRAINDICATIONS

There are few specific contraindications to immunotherapy in properly diagnosed patients. General contraindications include:

EXTREME SENSITIVITY TO THE SPECIFIC ALLERGEN - Determined by documentation of previous anaphylaxis following allergen exposure.

AUTOIMMUNE DISEASE - Animals with autoimmune disease may be at increased risk, due to the possibility that routine immunizations could exacerbate underlying disease.

REACTIONS

Allergenic Extracts have the potential during immunotherapy to cause serious local or systemic reactions. Patients receiving Allergenic Extracts should be kept under observation for a minimum of 30 minutes so that any adverse reaction can be observed and properly handled (See OVERDOSAGE).

Pet owners should be informed of these risks prior to beginning immunotherapy. Immunotherapy doses should be lowered or temporarily withheld from the patient if reactions occur. Reactions could include itchiness of the mouth, swelling or redness of the skin, hives, pruritis, rhinitis, difficulty breathing, heightened agitation, GI upset (vomiting, diarrhea) or lethargy. Though highly unlikely, severe reactions could include swelling of the throat, hypotension, anaphylaxis, loss of consciousness, or death.

OVERDOSAGE

Systemic allergic reactions may occur as a result of immunotherapy. If the patient receives more Allergenic Extract than can be tolerated at a specific time point and begins to experience immediate hypersensitivity-mediated systemic reactions, properly trained personnel should be available, with the following medications on hand:

A. Epinephrine
B. Injectable antihistamine (e.g. Diphenhydramine)
C. Injectable fast-acting corticosteroid (e.g. Hydrocortisone or Cortisone)
D. Oral antihistamines (e.g. Hydroxyzine, Diphenhydramine or Chloropheniramine)

IMMUNOTHERAPY ROUTE OF ADMINISTRATION

Before administering treatment, inspect all patient and treatment information on the vials and included documentation to ensure the correct products were received.

Sublingual Immunotherapy is administered with a metered dose pump under the tongue or inside the cheek, adjacent to the gum. Dosage of Allergenic Extracts may be further individualized according to the patient's sensitivity, clinical response, and tolerance to the extract. Immunotherapy drops are usually given one drop daily for the first 7 days of the protocol increasing to 2 drops (canine/feline patients) or 3 drops (equine patients) daily until the maintenance dose is reached.

When beginning patients on refill or higher concentration vials, follow the induction schedule to ease the patient's transition to potentially more potent vials.

SEE FRONT FOR DOSING INSTRUCTIONS.

HOW SUPPLIED

Allergenic Extract Prescription Product Sublingual Immunotherapy is supplied as an initial treatment set consisting of up to three vials of Allergenic Extract with increasing protein antigen concentration and a maintenance treatment set consisting of a single vial. Up to two sets of vials may be supplied for each prescription. Metered dose pumps are included with treatment vials.

STORAGE

Sublingual Allergenic Extracts must be stored upright at 2-8°C (35-45°F). DO NOT FREEZE. Refer to vial labels for expiration dates.