Canine Atopic Dermatitis Immunotherapeutic
For Use in Dogs Only
Cytopoint™ aids in the reduction of clinical signs associated with atopic dermatitis in dogs. Cytopoint™ is a ready-to-use, sterile liquid containing a caninized monoclonal antibody (mAb) against interleukin-31 (IL-31). IL-31 has been shown to induce pruritus in dogs in laboratory studies. Cytopoint™ remains in circulation for several weeks. It exerts a therapeutic effect by binding to and neutralizing soluble IL-31, thus inhibiting pruritus and reducing skin lesions. Like other naturally-occurring antibodies and antibody-antigen complexes, elimination is via normal protein degradation pathways.

SAFETY: A field safety study has demonstrated that Cytopoint™ is well-tolerated in dogs after subcutaneous injection. Adverse events occurred at a similar frequency between treated and placebo groups in a study of 245 canine patients presented to veterinary hospitals and diagnosed with atopic dermatitis. In this study, dogs were administered Cytopoint™ (1.0-3.3 mg/kg body weight) or placebo by the subcutaneous route on Days 0 and 28. Signs of patient discomfort on administration and adverse events occurred at a similar frequency between treatment groups. In addition, there was no clinically important difference in clinical pathology changes between groups following either dose. A wide variety of concomitant medications were safely used, including antihistamines and other antipruritics, such as oclacitinib and cyclosporine.

Cytopoint™ has also been demonstrated to be well-tolerated in dogs in a laboratory safety study in which 7 consecutive monthly subcutaneous injections were administered at doses of 3.3 mg/kg body weight (12 dogs per group). Significant changes on hematologic parameters were observed in 2 dogs following the 2nd injection and in 5 dogs following the 5th injection. No significant changes on clinical pathology parameters were observed.

DIRECTIONS:
For convenience, the dosing tables below may be used as a guideline. Repeat administration every 4-8 weeks as needed in individual patients.

In a study of 211 canine patients presented to veterinary hospitals and diagnosed with atopic dermatitis. In this study, dogs were administered Cytopoint™ (1.0-3.3 mg/kg body weight) or placebo on Day 0. Fifty dogs were treated with 2.0 mg/kg of Cytopoint™ and 52 dogs were treated with placebo on Day 0. *Significantly different compared to placebo (P<0.05)

**Dogs weighing <5.0 lb (<2.3 kg):**
Aseptically withdraw 0.09 mL/lb (0.2 mL/kg) from a single, 10-mg (Sky) vial and administer subcutaneously. Discard any remaining product.

**Dogs weighing 5.0-40 lb (2.3-18.1 kg):**
Aseptically withdraw the full volume of the appropriate vial according to the dosage table below and administer subcutaneously as a single injection.

**Dogs weighing >40 lb (18.1 kg):**
A single dose requires a combination of vials, as outlined in the table below. Prior to administration, collect the number of vials indicated under each presentation according to the dog’s body weight. Aseptically draw the full volume from each vial into one syringe and administer subcutaneously as a single injection.

**Treatment Success: Veterinary Assessment of CADESI-03 50% Reduction vs Baseline**

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Aseptically withdraw 0.09 mL/lb (0.2 mL/kg) from a single, 10-mg (Sky) vial and administer subcutaneously. Discard any remaining product.

**Dogs weighing >5.0-40 lb (2.3-18.1 kg):**
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**Dogs weighing >40 lb (18.1 kg):**
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**TREATMENT SUCCESS: OWNER ASSESSMENT OF PRURITUS VAS**

**PRESERVATIVES:**
1. The product does not have a preservative. Each vial is for single use only. Inactivate unused contents.
2. This product is intended for subcutaneous use only.
3. Store upright at 2°-8°C. Prolonged exposure to higher temperatures and/or direct sunlight may adversely affect potency. Do not freeze.
4. Use entire contents when first opened.
5. Sterilized syringes and needles should be used to administer this product. Do not sterilize with chemicals because traces of disinfectant may inactivate the product.
6. This product has not been tested in pregnant, lactating or breeding animals.
7. Do not mix with other products.
8. In case of human exposure, contact a physician.

For use by, or under the supervision of, a veterinarian.

Technical inquiries should be directed to Zoetis Inc. Veterinary Services, (888) 963-8471 (USA), (800) 461-0917 (Canada).

This product has been shown to be efficacious in treating healthy dogs with canine atopic dermatitis.

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Zoetis Inc.
Kalamazoo, MI 49007, USA

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