CYTOPOINT™

See productdata.aphis.usda.gov for a summary of the studies approved by the USDA for licensing this product. This package insert also contains additional information developed by the licensee.

Canine Allergic Dermatitis Immunotherapeutic
For Use in Dogs Only

This product has been shown to be effective for the treatment of dogs against allergic dermatitis and atopic dermatitis. For more information regarding efficacy and safety data, go to productdata.aphis.usda.gov.

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 the safety of Cytopoint after subcutaneous injection under typical use conditions. 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. There was no clinically relevant difference in rates of adverse events, including signs of patient discomfort on administration, between treated and placebo groups in the study of 245 canine patients (presented to veterinary hospitals and diagnosed with atopic dermatitis). 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 parasiticides, antibiotics, antifungals, corticosteroids, vaccines, allergen-specific immunotherapy, antihistamines and other antipruritics, such as oclacitinib and cyclosporine.
Cytopoint has also been demonstrated to be safe in dogs in a laboratory safety study in which 7 consecutive monthly subcutaneous injections were administered at doses of 3.3 mg/kg or 10 mg/kg body weight (12 dogs per group).

EFFECTIVENESS: In a study of 211 canine patients presented to veterinary hospitals and diagnosed with atopic dermatitis, a single dose of Cytopoint (up to 2.0 mg/kg) or placebo was administered subcutaneously. The study demonstrated a treatment effect for at least one month at a dose of 2.0 mg/kg. Treatment success measures were based on the owner assessment of pruritus (Visual Analog Scale; VAS) scores and veterinarian assessment of skin lesion scores (Canine Atopic Dermatitis Extent and Severity Index; CADESI-03).[1]
In a laboratory study using a canine model of IL-31-induced pruritus, a single dose of Cytopoint (2.0 mg/kg) or placebo was administered subcutaneously. This product has been shown to effectively reduce IL-31-induced pruritus within one day and at day 28 in Cytopoint-treated dogs compared to placebo-treated dogs.

DIRECTIONS:
Cytopoint is available in 1-mL vials in four concentrations (10, 20, 30 or 40 mg). Administer Cytopoint at a minimum dose of 0.9 mg/lb (2 mg/kg) body weight. For convenience, the dosing tables below may be used as a guideline. Repeat administration every 4-8 weeks as needed in individual patients.

The product does not contain a preservative. Each vial is for single use only. Inactivate unused contents.

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.

Dog Body Weight in **Pounds**	Dog Body Weight in **Kilograms**	**Presentation**			
		10 mg (Sky)	**20 mg (Plum)**	**30 mg (Blush)**	**40 mg (Navy)**
5.0-10	**2.3-4.5**	**1 vial**			
10.1-20	**4.6-9.1**		**1 vial**		
20.1-30	**9.2-13.6**			**1 vial**	
30.1-40	**13.7-18.1**				**1 vial**

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.

Dog Body Weight in **Pounds**	Dog Body Weight in **Kilograms**	**Presentation**			
		10 mg (Sky)	**20 mg (Plum)**	**30 mg (Blush)**	**40 mg (Navy)**
40.1-50	**18.2-22.7**	**1 vial +**			**1 vial**
50.1-60	**22.8-27.2**		**1 vial +**		**1 vial**
60.1-70	**27.3-31.7**			**1 vial +**	**1 vial**
70.1-80	**31.8-36.3**				**2 vials**
80.1-90	**36.4-40.8**	**1 vial +**			**2 vials**
90.1-100	**40.9-45.4**		**1 vial +**		**2 vials**
100.1-110	**45.5-49.9**			**1 vial +**	**2 vials**
110.1-120	**50.0-54.4**				**3 vials**
120.1-130	**54.5-59.0**	**1 vial +**			**3 vials**
130.1-140	**59.1-63.5**		**1 vial +**		**3 vials**
140.1-150	**63.6-68.0**			**1 vial +**	**3 vials**
150.1-160	**68.1-72.6**				**4 vials**
160.1-170	**72.7-77.1**	**1 vial +**			**4 vials**
170.1-180	**77.2-81.6**		**1 vial +**		**4 vials**
180.1-190	**81.7-86.2**			**1 vial +**	**4 vials**
190.1-200	**86.3-90.7**				**5 vials**

PRECAUTIONS:
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.
9. Based on voluntary post-approval global adverse product experience reporting, the following adverse events have been observed in rare cases (more than 1 but less than 10 animals in 10,000 dogs treated):
   - Hypersensitivity reactions (anaphylaxis, facial edema, urticaria). In such cases, appropriate treatment should be administered immediately.
   - Vomiting and/or diarrhea; may also occur in connection with hypersensitivity reactions.
   - Neurological signs (seizure or ataxia).

   The following adverse events have been observed in very rare cases (<1 animal in 10,000 dogs treated): clinical signs of immune-mediated diseases (e.g. immune-mediated hemolytic anemia, immune-mediated thrombocytopenia).
10. Cytopoint may induce transient or persistent anti-drug antibodies. The induction of such antibodies is uncommon and may have no effect (transient anti-drug antibodies) or may result in a noticeable decrease in efficacy (persistent anti-drug antibodies) in animals that responded to treatment previously.

REFERENCES:
1. Michels GM, Ramsey DS, Walsh KF, *et. al*: A blinded, randomized, placebo-controlled, dose determination trial of lokivetmab (ZTS-00103289), a caninized, anti-canine IL-31 monoclonal antibody in client owned dogs with atopic dermatitis. *Vet Dermatol* 2016; 27: 478-e129

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

Technical inquiries should be directed to Zoetis Inc. Veterinary Services, (888) 963-8471.

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