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.

Canine Allergic Dermatitis Immunotherapeutic

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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 parasitides, antibiotics, antihistamis, 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/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).

In a laboratory study using a canine model of IL-31-induced pruritus, a single dose of Cytopoint (0.2 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 0.5 mg/kg (2 mg/kg) body weight. For convenience, the dosing tables below may be used as a guideline. Repeat administration every 4–6 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 > 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.

Asceptically draw the full volume from each vial into one syringe and administer subcutaneously as a single injection.

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.

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