Product Name: CYTOPOINT Solution for Injection for Dogs 30 mg
APVMA Approval No: 83545/120340

Label Name:	CYTOPOINT Solution for Injection for Dogs 30 mg

Signal Headings:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY

Constituent Statements:	Each 1 mL vial contains 30 mg lokivetmab

Claims:	For use by or under direction of a registered veterinarian. For the treatment of the clinical manifestations of atopic dermatitis in dogs.

Net Contents:	2 x 1 mL 6 x 1 mL

Directions for Use:	

Restraints:	

Contraindications:	Do not use in case of hypersensitivity to lokivetmab. Do not use in dogs less than 3 kg bodyweight. Do not mix with any other veterinary medicinal product.

Precautions:	When administering vaccines at the same time as CYTOPOINT, it is advised that each injection be given at different sites. The safety of CYTOPOINT has not been established during pregnancy and lactation; therefore its use is not recommended during pregnancy or lactation. In cases of atopic dermatitis, it is recommended to investigate and treat complicating factors such as bacterial, fungal or parasitic infections/infestations (e.g. flea and mange). It is recommended to monitor dogs for bacterial infections associated with atopic dermatitis, especially during the first weeks of lokivetmab treatment. If no or limited response is observed within one month after initial dosing, an improvement in response may be observed after administration of a second dose one month later.

	However, if the animal does not show a better response after the second dose, the veterinarian should consider alternative treatments.

Side Effects:	In rare cases hypersensitivity reactions (anaphylaxis, facial oedema, urticaria) may occur. In such cases appropriate treatment should be administered without delay. Lokivetmab may induce transient or persistent anti-drug antibodies. The induction of such antibodies may reduce the efficacy of the product.

Dosage and Administration:	Remove the glass vial(s) from the carton at time of monthly treatment, withdraw all the liquid from the vial using a needle and syringe and inject the contents subcutaneously in the shoulder region. For dogs above 40 kg, the contents of more than one vial are required to constitute a single dose. In those cases, withdraw the entire contents from each required vial into the same syringe. To allow for mixing of the solution, gently invert the syringe three or four times before administering. Avoid excessive shaking or foaming of the liquid. The recommended minimum dose of CYTOPOINT is 1 mg/kg bodyweight (maximum 3.3 mg/kg), administered subcutaneously once a month. This dose range can be achieved using the suggested dosing regime in the table below: [insert dose rate table which has not changed] This section contains file attachment.

General Directions:	Lokivetmab is a caninised monoclonal antibody (mAb) specifically targeting canine interleukin-31 (IL-31). The blocking of IL-31 by lokivetmab prevents IL-31 from binding to its co-receptor and thereby inhibits IL-31 mediated cell signalling, providing relief from atopic dermatitis-related pruritus and inflammation. In a laboratory model study lokivetmab demonstrated an onset of efficacy for pruritus by the first time point at 8 hours post administration. No drug interactions were observed in the field studies when lokivetmab was administered concomitantly with veterinary medicines such as endo- and ectoparasiticides, antimicrobials, anti-inflammatories and vaccines. In field studies up to 3 months, some dogs showed a low or an absence of clinical response to lokivetmab. This is likely due to the highly targeted mechanism of action of lokivetmab in the context of a complex disease and heterogeneous pathogenesis.

Withholding Periods:	

Trade Advice:	

Safety Directions:	

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

First Aid Warnings:	

Additional User Safety:	Take care to avoid accidental self-injection. Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection. Accidental self-injection may result in an immune response to lokivetmab. It is not expected for this to cause any adverse effects, however, repeated self-administration may increase risk of hypersensitivity reactions, including anaphylaxis. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Environmental Statements:	

Disposal:	Dispose of empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

Storage:	Store between 2 °C to 8 °C (Refrigerate, do not freeze). Store in the original package. Protect from light. Avoid excessive shaking.

	Cytopoint strength (mg) to be administered monthly			
Bodyweight (kg)	**10**	**20**	**30**	**40**
3.0 – 10.0	1 vial			
10.1 – 20.0		1 vial		
20.1 – 30.0			1 vial	
30.1 – 40.0				1 vial
Dogs over 40.1 kg require 2 vials as below.				
40.1 – 50.0	1 vial			1 vial
50.1 – 60.0			2 vials	
60.1 – 70.0			1 vial	1 vial
70.1 – 80.0				2 vials