CYTOPOINT® SOLUTION FOR INJECTION FOR DOGS

PRESENTATION

Each vial of 1 ml contains 10, 20, 30 or 40 mg Lokivetmab.

Lokivetmab is a caninised monoclonal antibody expressed through recombinant techniques in Chinese hamster ovary (CHO) cells.

USES

Indicated for the treatment of clinical manifestations of atopic dermatitis in dogs.

DOSAGE AND ADMINISTRATION

For subcutaneous use. Avoid excessive shaking or foaming of the solution. Administer the entire contents (1 ml) of the vial.

Dose according to the dosing chart below. For dogs above 40 kg, the contents of more than one vial are required to administer in a single dose. In those cases, withdraw the appropriate content 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.

Dosage and treatment schedule:

The recommended minimum dose is 1 mg/kg bodyweight, once a month. Dose according to the dosing chart below:

Bodyweight (kg) of dog	Cytopoint strength (mg) to be administered			
	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
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

CONTRA-INDICATIONS, WARNINGS, ETC

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs less than 3 kg bodyweight.

Lokivetmab 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.

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 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 veterinary surgeon should consider alternative treatments.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation; therefore its use is not recommended during pregnancy, lactation or in breeding animals.

No drug interactions were observed in field studies where lokivetmab was administered concomitantly with veterinary medicinal products such as endo- and ectoparasiticides, antimicrobials, anti-inflammatories and vaccines.

If a vaccine(s) is to be administered at the same time as treatment with lokivetmab, the vaccine(s) should be administered at a different site to that of lokivetmab administration.

Do not mix with any other veterinary medicinal product.

Hypersensitivity reactions (anaphylaxis, facial oedema, urticaria) may occur in rare cases. In such cases appropriate treatment should be administered immediately.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

No adverse reactions other than those mentioned above were observed in laboratory overdose studies. In case of adverse clinical signs after an overdose the dog should be treated symptomatically.

User warnings:

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 the risk of hypersensitivity reactions.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

PHARMACEUTICAL PRECAUTIONS

Store in a refrigerator (2°C - 8°C)

Do not freeze.

Store in the original package. Protect from light.

Shelf life after first opening the immediate packaging: use immediately

Keep out of the sight and reach of children.

For animal treatment only.

LEGAL CATEGORY

POM-V

PACKAGING QUANTITIES

Supplied in boxes with 2 or 6 single dose vials.

Not all pack sizes may be marketed.

FURTHER INFORMATION

Lokivetmab is a caninised monoclonal antibody (mAb) specifically targeting canine interleukin-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 anti-inflammatory activity.

In a laboratory model study lokivetmab demonstrated an onset of efficacy for pruritus by the first time point at 8 hours post administration.

In field studies up to 9 months, treatment of dogs with atopic dermatitis was demonstrated to have a favourable effect on the reduction of pruritus and on the reduction of disease severity as evaluated by Canine Atopic Dermatitis Extent and Severity Index (CADESI) 03 scores. A small number of 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.

Disposal advice:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION NUMBER

EU/2/17/205/001-008