SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 10 mg solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:
Active substance:

Lokivetmab* 10 mg

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

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear to opalescent solution without any visible particles.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of pruritus associated with allergic dermatitis in dogs.

Treatment of clinical manifestations of atopic dermatitis in dogs.

4.3 Contraindications

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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
Avoidance or elimination of the allergen is an important consideration in the successful treatment of allergic dermatitis. When treating pruritus associated with allergic dermatitis with lokivetmab, investigate and treat any underlying causes (e.g. flea allergic dermatitis, contact dermatitis, food hypersensitivity); this product is not intended to be used as a long-term maintenance therapy if the offending allergen(s) can be successfully avoided or eliminated. Furthermore, in cases of allergic dermatitis and 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[1] (anaphylaxis, facial oedema, urticaria) Vomiting[2], diarrhoea[2] Neurological signs (ataxia, convulsion, seizure)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain, injection site swelling Clinical signs of immune mediated diseases (e.g. immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia)

[1] In case of such reactions, appropriate treatment should be administered immediately.

[2] May occur in connection with hypersensitivity reactions. Treatment should be administered as needed.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.

Fertility:

Do not use in breeding animals.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amount(s) to be administered and administration route

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 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.

<u>Dosage and treatment schedule:</u>

The recommended minimum dose is 1 mg/kg bodyweight, once a month. The need for repeat or longer-term treatment in dogs with allergic dermatitis should be based on the needs of the individual patient, including an assessment by the responsible veterinarian of the ability to avoid/eliminate the allergenic stimulus (see also section 4.5).

Dose according to the dosing chart below:

-	- **CYTOPOINT strength (mg) and number of vials to be administered**			
- **Bodyweight (kg) of dog**	- **10 mg**	- **20 mg**	- **30 mg**	- **40 mg**
- 3.0-10.0	- **1**	-	-	-
- 10.1-20.0	-	- **1**	-	-
- 20.1-30.0	-	-	- **1**	-
- 30.1-40.0	-	-	-	- **1**
- 40.1-50.0	- **1**	-	-	- **1**
- 50.1-60.0	-	-	- **2**	-
- 60.1-70.0	-	-	- **1**	- **1**
- 70.1-80.0	-	-	-	- **2**

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those mentioned in section 4.6 were observed in laboratory overdose studies.

In case of adverse clinical signs after an overdose the dog should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other dermatological preparations. Agents for dermatitis, excluding corticosteroids.

ATCvet code: QD11AH91

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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. Refer also to section 4.5 of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Histidine
Histidine hydrochloride monohydrate
Trehalose dihydrate
Disodium edetate
Methionine
Polysorbate 80
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Store in the original package.
Protect from light.

6.5 Nature and composition of immediate packaging

Single dose clear glass Type I vials with chlorobutyl rubber stopper.

Pack sizes:
CYTOPOINT 10 mg solution for injection for dogs:
Cardboard box with 1 vial of 1 ml, 2 vials of 1 ml or 6 vials of 1 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5017

9. DATE OF FIRST AUTHORISATION

25 April 2017

10. DATE OF REVISION OF THE TEXT

December 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Approved 08 December 2023