SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 40 mg solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each vial of 1 ml contains:

CYTOPOINT 40 mg:
Lokivetmab* 40 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.
The product should appear clear to opalescent without any visible particle.

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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions (anaphylaxis, facial oedema, urticaria) have been reported to occur in rare cases from spontaneous reports. In such cases appropriate treatment should be administered immediately.

Vomiting and/or diarrhoea have been reported to occur in rare cases from spontaneous reports and may occur in connection with hypersensitivity reactions. Treatment should be administered as needed.

Neurological signs (seizure, convulsion or ataxia) have been rarely observed in spontaneous reports following use of the veterinary medicinal product.

Application site disorders (injection site pain, injection site swelling) have been reported very rarely in spontaneous reports.

Clinical signs of immune-mediated diseases, such as haemolytic anaemia or thrombocytopenia, have been reported very rarely in spontaneous reports.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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.

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 administration.

4.9 Amounts 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. IMMUNOLOGICAL PROPERTIES

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

ATC vet code: QD11AH91

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. 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

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

Secondary packaging: cardboard box.
Pack sizes:
CYTOPOINT 40 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

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 42058/5020

9. DATE OF FIRST AUTHORISATION

25 April 2017

10. DATE OF REVISION OF THE TEXT

August 2021

Approved 27 August 2021