PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 20 mg solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml dose contains 20 mg lokivetmab.

3. PACKAGE SIZE

1 x 1 ml
2 x 1 ml
6 x 1 ml

4. TARGET SPECIES

 Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze.
Store in the original package. Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5018

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Vial / 1 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

lokivetmab 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

5. ROUTE(S) OF ADMINISTRATION

SC

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 20 mg solution for injection for dogs

2. COMPOSITION

Each 1 ml dose contains:

Active substance:
Lokivetmab* 20 mg

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

Clear to opalescent solution without any visible particles.

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

Treatment of pruritus associated with allergic dermatitis in dogs.
Treatment of clinical manifestations of atopic dermatitis in dogs.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 3 kg bodyweight.

6. SPECIAL WARNINGS

Special warnings:
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.

Special precautions for safe use in the target species:
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 obtained within one month after initial dosing, a second dose one month later may increase effectiveness. If the animal does not show a better response after a 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.

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.

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.

Overdose:
No adverse reactions other than those mentioned in section ”Adverse events” were observed in laboratory overdose studies.

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

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reaction[1] (anaphylaxis (severe allergic reaction), facial oedema (swelling), urticaria (hives)) 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 (low amounts of platelets))

[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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.

Dosage and treatment schedule:
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 ”Special warnings”).

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**

9. ADVICE ON CORRECT ADMINISTRATION

Avoid excessive shaking or foaming.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which stated on the carton and vial label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help to protect the environment.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

EU/2/17/205/001-012

Vm 42058/5018

Pack sizes:
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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

August 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey, KT22 7LP
UK
Tel: +44 (0) 345 300 8034

United Kingdom (Northern Ireland)
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
Cherrywood Business Park,
Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription

Approved 08 December 2023