LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 40 mg solution for injection for dogs
lokivetmab

2. STATEMENT OF ACTIVE SUBSTANCES

Each vial of 1 ml contains 40 mg lokivetmab.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

 Dog.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5020

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL – 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 40 mg solution for injection for dogs
lokivetmab

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

lokivetmab 40 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
CYTOPOINT 40 mg solution for injection for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and Manufacturer responsible for batch release:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 40 mg solution for injection for dogs
lokivetmab

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

4. INDICATION(S)

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. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 12). 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 label after EXP.

Shelf life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

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.

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 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; therefore its use is not recommended during pregnancy, lactation or in breeding dogs.

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.

When administering vaccines at the same time as this veterinary medicinal product, it is advised that each injection be given at different sites.

Overdose (symptoms, emergency procedures, antidotes):

No adverse reactions other than those mentioned in section 6 were observed in laboratory overdose studies.

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

Incompatibilities:

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

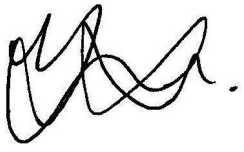
15. OTHER INFORMATION

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.



Approved: 11 August 2022