ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 10 mg solution for injection for dogs
CYTOPOINT 20 mg solution for injection for dogs
CYTOPOINT 30 mg solution for injection for dogs
CYTOPOINT 40 mg solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:

Lokivetmab*	10 mg
	20 mg
	30 mg
	40 mg

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

Excipients:

Qualitative composition of excipients and other constituents
Histidine
Histidine hydrochloride monohydrate
Trehalose dihydrate
Disodium edetate
Methionine
Polysorbate 80
Water for injections

Clear to opalescent solution without any visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 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.

3.4 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.

3.5 Special precautions for use

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 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.

3.6 Adverse events

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 the package leaflet for respective contact details.

3.7 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.

3.8 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.

3.9 Administration routes and dosage

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 3.5). 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**

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions other than those mentioned in section 3.6 were observed in laboratory overdose studies.

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QD11AH91

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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 3.5 of the SPC.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 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

CYTOPOINT 20 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

CYTOPOINT 30 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

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.

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

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/205/001-012

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25/04/2017.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT 10 mg solution for injection
CYTOPOINT 20 mg solution for injection
CYTOPOINT 30 mg solution for injection
CYTOPOINT 40 mg solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains 10 mg lokivetmab.
Each 1 ml dose contains 20 mg lokivetmab.
Each 1 ml dose contains 30 mg lokivetmab.
Each 1 ml dose contains 40 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 Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/205/009	10 mg/ml	1 vial
EU/2/17/205/001	10 mg/ml	2 vials
EU/2/17/205/002	10 mg/ml	6 vials
EU/2/17/205/010	20 mg/ml	1 vial
EU/2/17/205/003	20 mg/ml	2 vials
EU/2/17/205/004	20 mg/ml	6 vials
EU/2/17/205/011	30 mg/ml	1 vial
EU/2/17/205/005	30 mg/ml	2 vials
EU/2/17/205/006	30 mg/ml	6 vials
EU/2/17/205/012	40 mg/ml	1 vial
EU/2/17/205/007	40 mg/ml	2 vials
EU/2/17/205/008	40 mg/ml	6 vials

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL – 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CYTOPOINT

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

lokivetmab 10 mg/ml
lokivetmab 20 mg/ml
lokivetmab 30 mg/ml
lokivetmab 40 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CYTOPOINT 10 mg solution for injection for dogs
CYTOPOINT 20 mg solution for injection for dogs
CYTOPOINT 30 mg solution for injection for dogs
CYTOPOINT 40 mg solution for injection for dogs

2. Composition

Each 1 ml dose contains:

Active substance:

Lokivetmab*	10 mg
	20 mg
	30 mg
	40 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 periods

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 or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

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

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

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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:

België/Belgique/Belgien
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Mercuriusstraat 20
BE-1930 Zaventem
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