ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lenivia 0.5 mg solution for injection for dogs
Lenivia 1.0 mg solution for injection for dogs
Lenivia 1.5 mg solution for injection for dogs
Lenivia 2.0 mg solution for injection for dogs
Lenivia 3.0 mg solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 1 ml contains:

Active substances:

izenivetmab*: 0.5 mg
1.0 mg
1.5 mg
2.0 mg
3.0 mg

* Izenivetmab is a caninised monoclonal antibody targeting canine nerve growth factor (NGF) expressed through recombinant techniques in Chinese hamster ovary (CHO) cells.

Excipients:

Qualitative composition of excipients and other constituents
L-histidine
Histidine hydrochloride monohydrate
Trehalose dihydrate
Disodium EDTA dihydrate
L-methionine
Poloxamer 188
Water for injections

Clear to slightly opalescent solution without any visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the reduction of pain associated with osteoarthritis (OA) 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 under 12 months.

Do not use in animals intended for breeding.
Do not use in pregnant or lactating animals.

3.4 Special warnings

This veterinary medicinal product may induce anti-drug antibodies. The induction of such antibodies in a 9-month repeat-dose clinical trial for safety and efficacy was observed in 3.46% (10/289) of dogs. Anti-drug antibodies were associated with lower serum izenivetmab concentrations and loss of efficacy. There were no adverse events (AEs) related to the presence of anti-drug antibodies (immunogenicity). Immunogenicity has not been investigated in dogs previously treated with other anti-NGF monoclonal antibodies.

A waning of effect was seen towards the end of each treatment interval in the clinical trial. A clinically sufficient reduction of pain may not be achieved for all dogs, particularly the dogs suffering from severe OA. If no or limited response is observed after the initial dosing, or if the effect is not maintained throughout the 3-month dosing interval, switching to alternative treatment is recommended.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Where a dog has not been able to properly exercise prior to treatment due to its clinical condition, it is recommended that the dog is gradually (over a few weeks) allowed to increase the amount of exercise it takes (to prevent overexercise by some dogs).

In the clinical trials, joint radiographs were only taken at screening. Therefore, potential negative effects on the progression of the osteoarthritis have not been investigated.

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. Repeated accidental self-injection may increase the risk of hypersensitivity reactions.

In humans, minor and reversible peripheral neurological signs (for example, paraesthesia, dysesthesia, hypoesthesia) have been reported in a small subset of patients receiving therapeutic doses of human anti-NGF monoclonal antibodies. The frequency of these events is dependent on factors such as dose level and duration of dosing. These events were transitory and reversible upon discontinuation of treatment.

The importance of nerve growth factor in ensuring normal foetal nervous system development is well-established, and laboratory studies conducted on non-human primates with human anti-NGF antibodies have shown evidence of reproductive and developmental toxicity. Pregnant women, women trying to conceive, and breastfeeding women should take extreme care to avoid accidental self-injection.

If adverse effects occur following accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Immediate pain upon injection
Uncommon (1 to 10 animals / 1 000 animals treated):	Ataxia, polydipsia, polyuria
Rare (1 to 10 animals / 10 000 animals treated):	Lethargy, anorexia
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction (facial swelling)[1], immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia

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

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 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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in breeding dogs. Laboratory studies with human anti-NGF antibodies in cynomolgus monkeys have shown evidence of teratogenic and foetotoxic effects.

Pregnancy and lactation:

Do not use in pregnant or lactating animals.

Fertility:

Do not use in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

There are no safety data on the concurrent long-term use of NSAIDs and izenivetmab in dogs. In clinical trials in humans, rapidly progressive osteoarthritis has been reported in patients receiving humanised anti-NGF monoclonal antibody therapy. The incidence of these events increased with high doses and in those human patients that received long-term (more than 90 days) non-steroidal anti-inflammatory drugs (NSAIDs) concomitantly with an anti-NGF monoclonal antibody.

No laboratory studies on the safety of concomitant administration of this veterinary medicinal product with other veterinary medicinal products have been conducted. No interactions were observed in clinical trials where this veterinary medicinal product was administered concomitantly with veterinary medicinal products including systemic antibacterials and antiparasitics.

If a vaccine(s) is to be administered at the same time as treatment with the veterinary medicinal product, the vaccine(s) should be administered at a different site to that of the veterinary medicinal product administration.

3.9 Administration routes and dosage

Subcutaneous use.

Administer the entire contents (1 ml) of the vial.

Dosage and treatment schedule:

The recommended dose is 0.05-0.1 mg/kg body weight, once every three months.

Dose according to the dosing chart below.

Body weight (kg) of dog	Lenivia number of vials to be administered				
	0.5 mg	1.0 mg	1.5 mg	2.0 mg	3.0 mg
5.0 – 10.0	1 vial				
10.1 – 20.0		1 vial			
20.1 – 30.0			1 vial		
30.1 – 40.0				1 vial	
40.1 – 60.0					1 vial
60.1 – 80.0				2 vials	
80.1 – 100.0				1 vial	1 vial
100.1 – 120.0					2 vials

For dogs weighing < 5.0 kg: aseptically withdraw 0.1 ml/kg from a single 0.5 mg vial and administer subcutaneously. For volumes ≤ 0.5 ml, use a 1.0 or 0.5 ml syringe and dose to the nearest 0.1 ml. Discard the remainder volume present in the vial.

For dogs of 60.1 kg and above, the contents of more than one vial are required. In those cases, withdraw the content from each required vial into the same syringe and administer as a single dose.

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

In an overdose study, two out of eight animals administered 6X overdose showed a minimal neuronal atrophy and increased density of glial cells in one ganglion (cranial mesenteric). These findings were not associated with clinical signs.

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: QN02BG93

4.2 Pharmacodynamics

Mechanism of action:

Izenivetmab is a caninised monoclonal antibody (mAb) targeting nerve growth factor (NGF). NGF binds to TrkA receptors located on immune cells to elicit the release of additional proinflammatory mediators, including NGF itself. These inflammatory mediators lead to further peripheral sensitisation involved in pain perception. The inhibition of NGF has demonstrated to provide relief from pain associated with osteoarthritis.

Clinical trials:

In clinical trials lasting up to 9 months, treatment of dogs with osteoarthritis was demonstrated to have a favourable effect on the reduction of pain assessed by the Canine Brief Pain Inventory (CBPI). CBPI is an assessment by the animal owner of an individual dog's response to pain treatment as assessed by pain severity (scale of 0 to 10, where 0 = no pain and 10 = extreme pain) and interference of pain with the dog's typical activities (scale of 0 to 10, where 0 = no interference and 10 = completely interferes). In the pivotal EU multicentre clinical trial, 37.3% (95/255) of the izenivetmab-treated dogs and 22.6% (58/257) of the placebo-treated dogs demonstrated treatment success, defined as a reduction of ≥ 1 in pain severity score (PSS) and ≥ 2 in pain interference score (PIS), on Day 90 after the first dose. An onset of efficacy was demonstrated at 7 days post administration, with treatment success demonstrated in 23.5% (63/268) of the izenivetmab-treated dogs and 11.9% (32/269) of the placebo-treated dogs. The PIS and PSS scores were reduced by approximately the same numerical values for mild, moderate and severe cases.

Additionally, examining veterinarians conducted a Veterinary Categorical Assessment (VCA) for three components: Lameness/Weight-bearing, Pain on Palpation/Manipulation of the Joint(s), and General Musculoskeletal Condition. Each component was independently scored as 'clinically normal', 'mild', 'moderate', 'severe', or 'nearly incapacitating'. An animal was defined as improved overall if either it had improved on at least one of the three scores and was not worse on any of the scores, or it had improved on at least two of the three scores and was worse on one or none of the scores. On day 90 following the initial dose, overall improvement compared to baseline (day 0) was observed in 68.1% (177/260) of the izenivetmab-treated dogs and 49.6% (129/260) of the placebo-treated dogs.

4.3 Pharmacokinetics

In a pre-clinical pharmacokinetic study in healthy adult Beagle dogs administered izenivetmab at the approved label dose (0.05 – 0.1 mg/kg), maximum serum drug concentration (C_{max}) following subcutaneous use was 0.414 mcg/ml and occurred at an average of 3 days post-dose. In pre-clinical trials in dogs, bioavailability following subcutaneous administration was 100% and the elimination half-life was approximately 10 days.

Exposure to izenivetmab increased proportionally to the dose between 0.1 - 0.6 mg/kg and no accumulation was observed with repeated dosing.

In a 9-month repeat-dose clinical trial for safety and efficacy of izenivetmab in dogs with OA, the elimination half-life was approximately 13 days.

Izenivetmab, like endogenous proteins, is expected to be degraded into small peptides and amino acids via normal catabolic pathways. Izenivetmab is not metabolised by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Store in the original package.
Protect from light.

5.4 Nature and composition of immediate packaging

Clear glass type I vials with fluorobutyl rubber stopper.

Pack sizes:

Cardboard box with 1 vial of 1 ml.
Cardboard box with 2 vials of 1 ml.
Cardboard box with 6 vials of 1 ml.

Not all pack sizes may be marketed.

5.5 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 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/2/25/355/001-015

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 21/11/2025.

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

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

SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:

The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: annually.
At the time of the submission of the annual statement, the MAH shall provide a written summary of a cumulative analysis (including the review of case narratives), at the level of VeDDRA preferred terms (PT), or groups of PTs as appropriate, for neurological, musculoskeletal and renal adverse events, respectively. The written summary should be recorded within the annual statement.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lenivia 0.5 mg Solution for injection 5.0 – 10.0 kg
Lenivia 1.0 mg Solution for injection 10.1 – 20.0 kg
Lenivia 1.5 mg Solution for injection 20.1 – 30.0 kg
Lenivia 2.0 mg Solution for injection 30.1 – 40.0 kg
Lenivia 3.0 mg Solution for injection 40.1 – 60.0 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 0.5 mg izenivetmab.
Each ml contains 1.0 mg izenivetmab.
Each ml contains 1.5 mg izenivetmab.
Each ml contains 2.0 mg izenivetmab.
Each ml contains 3.0 mg izenivetmab.

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

s.c.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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/2/25/355/001 (5.0 – 10.0 kg, 0.5 mg, 1 x 1 ml)
EU/2/25/355/002 (5.0 – 10.0 kg, 0.5 mg, 2 x 1 ml)
EU/2/25/355/003 (5.0 – 10.0 kg, 0.5 mg, 6 x 1 ml)
EU/2/25/355/004 (10.1 – 20.0 kg, 1.0 mg, 1 x 1 ml)
EU/2/25/355/005 (10.1 – 20.0 kg, 1.0 mg, 2 x 1 ml)
EU/2/25/355/006 (10.1 – 20.0 kg, 1.0 mg, 6 x 1 ml)
EU/2/25/355/007 (20.1 – 30.0 kg, 1.5 mg, 1 x 1 ml)
EU/2/25/355/008 (20.1 – 30.0 kg, 1.5 mg, 2 x 1 ml)
EU/2/25/355/009 (20.1 – 30.0 kg, 1.5 mg, 6 x 1 ml)
EU/2/25/355/010 (30.1 – 40.0 kg, 2.0 mg, 1 x 1 ml)
EU/2/25/355/011 (30.1 – 40.0 kg, 2.0 mg, 2 x 1 ml)
EU/2/25/355/012 (30.1 – 40.0 kg, 2.0 mg, 6 x 1 ml)
EU/2/25/355/013 (40.1 – 60.0 kg, 3.0 mg, 1 x 1 ml)
EU/2/25/355/014 (40.1 – 60.0 kg, 3.0 mg, 2 x 1 ml)
EU/2/25/355/015 (40.1 – 60.0 kg, 3.0 mg, 6 x 1 ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL – 1 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lenivia

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

izenivetmab

0.5 mg
1.0 mg
1.5 mg
2.0 mg
3.0 mg

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

Lenivia 0.5 mg solution for injection for dogs
Lenivia 1.0 mg solution for injection for dogs
Lenivia 1.5 mg solution for injection for dogs
Lenivia 2.0 mg solution for injection for dogs
Lenivia 3.0 mg solution for injection for dogs

2. Composition

Active substances:

Each vial of 1 ml contains 0.5 mg, 1.0 mg, 1.5 mg, 2.0 mg or 3.0 mg izenivetmab*.

* Izenivetmab is a caninised monoclonal antibody targeting canine nerve growth factor (NGF) expressed through recombinant techniques in Chinese hamster ovary (CHO) cells.

Clear to slightly opalescent solution without any visible particles.

3. Target species

Dogs.

4. Indications for use

For the reduction of pain associated with osteoarthritis (OA) in dogs.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs under 12 months.
Do not use in animals intended for breeding.
Do not use in pregnant or lactating animals.

6. Special warnings

Special warnings:
This veterinary medicinal product may induce anti-drug antibodies. The induction of such antibodies in a 9-month repeat-dose clinical trial for safety and efficacy was observed in 3.46% (10/289) of dogs. Anti-drug antibodies were associated with lower serum izenivetmab concentrations and loss of efficacy. There were no adverse events (AEs) related to the presence of anti-drug antibodies (immunogenicity). Immunogenicity has not been investigated in dogs previously treated with other anti-NGF monoclonal antibodies.

A waning of effect was seen towards the end of each treatment interval in the clinical trial. A clinically sufficient reduction of pain may not be achieved for all dogs, particularly the dogs suffering from severe OA. If no or limited response is observed after the initial dosing, or if the effect is not maintained throughout the 3-month dosing interval, switching to alternative treatment is recommended.

Special precautions for safe use in the target species:
Where a dog has not been able to properly exercise prior to treatment due to its clinical condition, it is recommended that the dog is gradually (over a few weeks) allowed to increase the amount of exercise it takes (to prevent overexercise by some dogs).

In the clinical trials, joint radiographs were only taken at screening. Therefore, potential negative effects on the progression of the osteoarthritis have not been investigated.

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. Repeated accidental self-injection may increase the risk of hypersensitivity reactions.

In humans, minor and reversible peripheral neurological signs (for example, paraesthesia, dysesthesia, hypoesthesia) have been reported in a small subset of patients receiving therapeutic doses of human anti-NGF monoclonal antibodies. The frequency of these events is dependent on factors such as dose level and duration of dosing. These events were transitory and reversible upon discontinuation of treatment.

The importance of nerve growth factor in ensuring normal foetal nervous system development is well-established, and laboratory studies conducted on non-human primates with human anti-NGF antibodies have shown evidence of reproductive and developmental toxicity. Pregnant women, women trying to conceive, and breastfeeding women should take extreme care to avoid accidental self-injection.

If adverse effects occur following accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in breeding dogs. Laboratory studies with human anti-NGF antibodies in cynomolgus monkeys have shown evidence of teratogenic and foetotoxic effects.

Do not use in pregnant or lactating animals.

Fertility:
Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
There are no safety data on the concurrent long-term use of NSAIDs and izenivetmab in dogs. In clinical trials in humans, rapidly progressive osteoarthritis has been reported in patients receiving humanised anti-NGF monoclonal antibody therapy. The incidence of these events increased with high doses and in those human patients that received long-term (more than 90 days) non-steroidal anti-inflammatory drugs (NSAIDs) concomitantly with an anti-NGF monoclonal antibody.

No laboratory studies on the safety of concomitant administration of this veterinary medicinal product with other veterinary medicinal products have been conducted. No interactions were observed in clinical trials where this veterinary medicinal product was administered concomitantly with veterinary medicinal products including systemic antibacterials and antiparasitics.

If a vaccine(s) is to be administered at the same time as treatment with the veterinary medicinal product, the vaccine(s) should be administered at a different site to that of the veterinary medicinal product administration.

Overdose:
In an overdose study, two out of eight animals administered 6X overdose showed a minimal neuronal atrophy and increased density of glial cells in one ganglion (cranial mesenteric). These findings were not associated with clinical signs.

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

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Immediate pain upon injection
Uncommon (1 to 10 animals / 1 000 animals treated):	Incoordination (ataxia), increased thirst (polydipsia), increased need to urinate (polyuria)
Rare (1 to 10 animals / 10 000 animals treated):	Drowsiness (lethargy), loss of appetite (anorexia)
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction (facial swelling)[1], immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia

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

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 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.

Administer the entire contents (1 ml) of the vial.

Dosage and treatment schedule:
The recommended dose is 0.05-0.1 mg/kg body weight, once every three months.

Dose according to the dosing chart below.

Body weight (kg) of dog	Lenivia number of vials to be administered				
	0.5 mg	1.0 mg	1.5 mg	2.0 mg	3.0 mg
5.0 – 10.0	1 vial				
10.1 – 20.0		1 vial			
20.1 – 30.0			1 vial		
30.1 – 40.0				1 vial	
40.1 – 60.0					1 vial
60.1 – 80.0				2 vials	
80.1 – 100.0				1 vial	1 vial
100.1 – 120.0					2 vials

For dogs weighing < 5.0 kg: aseptically withdraw 0.1 ml/kg from a single 0.5 mg vial and administer subcutaneously. For volumes ≤ 0.5 ml, use a 1.0 or 0.5 ml syringe and dose to the nearest 0.1 ml. Discard the remainder volume present in the vial.

For dogs of 60.1 kg and above, the contents of more than one vial are required. In those cases, withdraw the content from each required vial into the same syringe and administer as a single dose.

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (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 is stated on the 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/25/355/001-015

Clear glass type I vials with fluorobutyl rubber stopper.
Cardboard box with 1, 2 or 6 vials of 1 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 and contact details to report suspected adverse events:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

België/Belgique/Belgien
Tél/Tel: +32 (0) 800 99 189
pharmvig-belux@zoetis.com

Република България
Тел: +359 888 51 30 30
zoetisromania@zoetis.com

Česká republika
Tel: +420 257 101 111
infovet.cz@zoetis.com

Danmark
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Deutschland
Tel: +49 30 2020 0049
tierarzneimittelsicherheit@zoetis.com

Eesti
Tel: +370 610 05088
zoetis.estonia@zoetis.com

Ελλάδα
Τηλ: +30 210 6791900
infogr@zoetis.com

España
Tel: +34 91 4191900
regulatory.spain@zoetis.com

Lietuva
Tel: +370 610 05088
zoetis.lithuania@zoetis.com

Luxembourg/Luxemburg
Tél/Tel: +32 (2) 746 80 11
pharmvig-belux@zoetis.com

Magyarország
Tel.: +36 1 224 5200
hungary.info@zoetis.com

Malta
Tel: +356 21 465 797
info@agrimedltd.com

Nederland
Tel: +31 (0)10 714 0900
pharmvig-nl@zoetis.com

Norge
Tlf: +47 23 29 86 80
adr.scandinavia@zoetis.com

Österreich
Tel: +43 (0)1 2701100 100
tierarzneimittelsicherheit@zoetis.com

Polska
Tel.: +48 22 2234800
pv.poland@zoetis.com

France
Tél: +33 (0)800 73 00 65
contacteznous@zoetis.com

Hrvatska
Tel: +385 1 6441 462
pv.westernbalkans@zoetis.com

Ireland
Tel: +353 (0) 1 256 9800
pvsupportireland@zoetis.com

Ísland
Sími: +354 540 8000
icepharma@icepharma.is

Italia
Tel: +39 06 3366 8111
farmacovigilanza.italia@zoetis.com

Κύπρος
Τηλ: +30 210 6791900
infogr@zoetis.com

Latvija
Tel: +370 610 05088
zoetis.latvia@zoetis.com

Portugal
Tel: +351 21 042 72 00
zoetis.portugal@zoetis.com

România
Tel: +40785019479
zoetisromania@zoetis.com

Slovenija
Tel: +385 1 6441 462
pv.westernbalkans@zoetis.com

Slovenská republika
Tel: +420 257 101 111
infovet.cz@zoetis.com

Suomi/Finland
Puh/Tel: +358 10 336 7000
laaketurva@zoetis.com

Sverige
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

United Kingdom (Northern Ireland)
Tel: +353 (0) 1 256 9800
pvsupportireland@zoetis.com