PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lenivia 2.0 mg solution for injection.
To treat body weight 30.1 – 40.0 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains 2.0 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

Subcutaneous use.

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 UK Limited

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5196

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGING UNITS
VIAL – 1 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lenivia

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

izenivetmab

2.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

PARTICULARS TO APPEAR ON THE 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 1 ml dose 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.

The product should appear clear to slightly opalescent without any visible particles.

3. Target species

Dogs.

4. Indications for use

For the alleviation 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 of age.
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 transient or persistent 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% of dogs. Anti-drug antibodies were associated with lower serum izenivetmab concentrations and in some dogs, lack of efficacy. There were no adverse events (AEs) related to the presence of anti-drug antibodies (immunogenicity). The safety and efficacy of the veterinary medicinal product has not been investigated in dogs previously administered other monoclonal antibody products.

A waning of effect was seen towards the end of each treatment interval in the pivotal clinical trial. A clinically sufficient reduction of pain may not be achieved for all dogs. If no or limited response is observed, 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

Caution should be used when treating patients with the following pre-existing conditions: immune- mediated haemolytic anaemia, immune-mediated thrombocytopenia.

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 neurologic 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.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product may cause eye irritation. Avoid contact with the eyes. In case of accidental contact with eyes, rinse thoroughly with water. If irritation persists, seek medical advice and show 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 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.

Dogs have no reported equivalent of human rapidly progressive osteoarthritis.

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

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.

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 case of adverse clinical signs after an overdose the dog should be treated symptomatically.
In a pivotal GLP margin of safety study, healthy Beagle dogs received up to 6-fold the intended therapeutic dose of izenivetmab on three occasions at 12-week intervals. No test article-related adverse effects were observed at any dose level during the complete duration of the study. Minor, non-adverse changes in body temperature were noted at the highest dose, with no associated clinical signs. One animal exhibited a weak, transient, non-neutralising ADA response without clinical impact. No accumulation was observed following repeated administration of the test article in this same study.

Special restrictions for use and special conditions for use:
Not applicable.

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):	Ataxia, increased thirst (polydipsia), increased need to urinate (polyuria)
Rare (1 to 10 animals / 10 000 animals treated):	Anorexia, lethargy
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:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Subcutaneous use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 5-60kg administer the entire contents (1ml) of the vial, according to the above table.

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 remaining volume present in the vial.

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

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

Vm 42058/5193
Vm 42058/5194
Vm 42058/5195
Vm 42058/5196
Vm 42058/5197

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
UK
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

17. Other information

POM-V

Mechanism of action:
Izenivetmab is a canine 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), interference of pain with the dog's typical activities (scale of 0 to 10, where 0 = no interference and 10 = completely interferes) and quality of life (assessed as 'poor', 'fair', 'good', 'very good' or 'excellent'). 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.

Gavin Hall

Approved: 22 May 2026