SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Librela 15 mg solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 1 ml contains:

Active substance:

bedinvetmab*: 15 mg

* Bedinvetmab is a canine monoclonal antibody expressed through recombinant techniques in Chinese hamster ovary (CHO) cells.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the alleviation of pain associated with osteoarthritis in dogs.

4.3 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.

4.4 Special warnings for each target species

This veterinary medicinal product may induce transient or persistent anti-drug antibodies.
The induction of such antibodies is uncommon and may have no effect or may result in a decrease in efficacy in animals that responded to treatment previously.

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.

4.5 Special precautions for use

i) Special precautions for use in animals

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 they take (to prevent overexercise by some dogs).

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

Caution should be used when treating patients with pre-existing seizure disorder.

ii) 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 self-administration may increase the risk of hypersensitivity reactions.

The importance of nerve growth factor (NGF) 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.

Special precautions for the protection of the environment:

Not applicable.

iii) Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reaction (e.g. injection site swelling, injection site warmth)[1].
Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, Emesis. Ataxia[2]. Polyuria, Urinary incontinence. Anorexia[3], Lethargy, Polydipsia.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (anaphylaxis, facial swelling, pruritus)[4], Immune-mediated haemolytic anaemia, Immune-mediated polyarthritis, Immune-mediated thrombocytopenia. Paresis, Paralysis, Seizure.

[1] Mild
[2] Including proprioceptive ataxia.
[3] Often related to a transient reduced appetite.
[4] 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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

In a laboratory study over a 2-week period in young, healthy dogs without osteoarthritis, this veterinary medicinal product had no adverse effect when

concomitantly administered with a non-steroidal anti-inflammatory product (carprofen).

There are no safety data on the concurrent long-term use of NSAIDs and bedinvetmab 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 other 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 field studies where this veterinary medicinal product was administered concomitantly with veterinary medicinal products containing parasiticides, antimicrobials, topical antiseptics with or without corticosteroids, antihistamines and vaccines.

If a vaccine(s) is to be administered at the same time as treatment with this veterinary medicinal product, the vaccine(s) should be administered at a different site to that of the veterinary medicinal products administration, to reduce any potential impact on immunogenicity of the vaccine.

4.9 Amount(s) to be administered and administration route

Subcutaneous use.

Dosage and treatment schedule:

The recommended dose is 0.5-1.0 mg/kg bodyweight, once a month

Dogs weighing <5.0 kg:
Aseptically withdraw 0.1 ml/kg from a single 5 mg/ml vial and administer subcutaneously.
For dogs between 5 and 60 kg administer the entire content of the vial (1 ml) according to the table below:

	Librela strength (mg) to be administered				
Bodyweight (kg) of dog	**5**	**10**	**15**	**20**	**30**
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**
100.1-120.00					**2 vials**

For dogs above 60 kg, 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 (2 ml).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions, except mild reactions at the injection site, were observed in a laboratory overdose study when the veterinary medicinal product was administered for 7 consecutive monthly doses at 10 times the maximum recommended dose.
In case of adverse clinical signs after an overdose the dog should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other analgesics and antipyretics.

ATCvet Code: QN02BG91

5.1 Pharmacodynamic properties

Mechanism of action:
Bedinvetmab is a canine monoclonal antibody (mAb) targeting nerve growth factor (NGF). The inhibition of NGF mediated cell signalling has demonstrated to provide relief from pain associated with osteoarthritis.

5.2 Pharmacokinetic particulars

In a 6-month laboratory study of healthy, adult Beagles administered bedinvetmab every 28 days at doses ranging from 1-10 mg/kg, AUC and C_{max} increased nearly in proportion to dose and steady-state was achieved after approximately 2 doses. In a laboratory pharmacokinetic study at the clinical label dose (0.5-1.0 mg/kg bw), peak serum drug levels (C_{max}) of 6.10 mcg/ml were observed at 2-7 days (t_{max} = 5.6 days) after subcutaneous dosing, the bioavailability was approximately 84%, the elimination half-life was approximately 12 days, and the mean $AUC_{0-\infty}$ was 141 mcg x d/ml.

In a field effectiveness study at the label dose in dogs with osteoarthritis, the terminal half-life averaged 16 days. Steady state was achieved after 2 doses.
Bedinvetmab, like endogenous proteins, is expected to be degraded into small peptides and amino acids via normal catabolic pathways. Bedinvetmab is not metabolised by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

Immunogenicity:
The presence of binding antibodies to bedinvetmab in dogs was assessed using a multitier approach. In field studies of dogs with osteoarthritis receiving bedinvetmab once monthly, the appearance of anti-bedinvetmab antibodies was infrequent. None

of the dogs exhibited any adverse clinical signs considered to be associated with binding antibodies to bedinvetmab.

Field trials:
In field studies lasting up to 3 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. In the pivotal EU multicentre field study, 43.5% of the Librela-treated dogs and 16.9% 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 28 after the first dose. An onset of efficacy was demonstrated at 7 days post administration, with treatment success demonstrated in 17.8% of the Librela-treated dogs and 3.8% of the placebo-treated dogs. Treatment with bedinvetmab has demonstrated a positive effect on all three components of the CBPI. Data from an uncontrolled follow-up study lasting up to 9 months indicated sustained efficacy of treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-histidine
Histidine hydrochloride monohydrate
Trehalose dihydrate
Disodium edetate
Methionine
Poloxamer 188
Water for injections

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4 Special precautions for storage

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

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5031

9. DATE OF FIRST AUTHORISATION

10 November 2020

10. DATE OF REVISION OF THE TEXT

January 2026

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 14 January 2026