

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Librela 5 mg Veterinary
Librela 10 mg Veterinary
Librela 15 mg Veterinary
Librela 20 mg Veterinary
Librela 30 mg Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each vial of 1 ml contains:

bedinvetmab*: 5 mg
10 mg
15 mg
20 mg
30 mg

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

Excipients:

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

The product should appear clear to slightly opalescent solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the alleviation of pain associated with osteoarthritis 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 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.

3.5 Special precautions for use

Special precautions for 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 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.

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.

3.6 Adverse events

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, Immunemediated Polyarthritits, Immune-mediated thrombocytopenia. Paresis, Paralysis, Seizure.
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¹Mild.

²Including proprioceptive ataxia.

³Often related to a transient reduced appetite.

⁴In case of such reactions, appropriate symptomatic treatment should be administered.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il/>.

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

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 product administration, to reduce any potential impact on immunogenicity of the vaccine.

3.9 Administration routes and dosage

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:

Bodyweight (kg) of dog	Librela strength (mg) to be administered				
	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).

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

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.

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: QN02BG91

4.2 Pharmacodynamics

Mechanism of action:

Bedinvetmab is a canine monoclonal antibody (mAb) targeting Nerve Growth Factor (NGF). The inhibition of NGF mediated cell signaling has demonstrated to provide relief from pain associated

with osteoarthritis.

4.3 Pharmacokinetics

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 $\mu\text{g/ml}$ 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 $\mu\text{g} \times \text{d/ml}$.

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 favorable 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Do not use the veterinary medicinal product after the expiry date (exp. date) mentioned on the package. The expiry date refers to the last day of that month.

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, 2 or 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

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

6. MARKETING AUTHORISATION HOLDER

Zoetis Israel Holding B.V.
5 Atir Yeda Street, Kfar Saba, Israel

7. MARKETING AUTHORISATION NUMBER

Librela 5 mg Veterinary: 180-18-37531-00
Librela 10 mg Veterinary: 180-19-37532-00
Librela 15 mg Veterinary: 180-20-37533-00
Librela 20 mg Veterinary: 180-21-37534-00
Librela 30 mg Veterinary: 180-22-37535-00

8. MANUFACTURER

Zoetis Belgium S.A.
Rue Laid Burniat 1, 1348 Louvain-la-Neuve, Belgium

9. DATE OF REVISION OF THE TEXT

Revised in January 2026