

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Librela 5 mg solution for injection for dogs
Librela 10 mg solution for injection for dogs
Librela 15 mg solution for injection for dogs
Librela 20 mg solution for injection for dogs
Librela 30 mg solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 1 ml contains:

Active substances:

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

* Bedinvetmab is a canine monoclonal antibody 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 edetate
Methionine
Poloxamer 188
Water for injections

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

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 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 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, Immune- mediated polyarthritis, 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 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

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 signalling 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 µg/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 µg 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.

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: 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 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/2/20/261/001-015

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 10/11/2020.

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

{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**

Librela 5 mg Solution for injection.
Librela 10 mg Solution for injection.
Librela 15 mg Solution for injection.
Librela 20 mg Solution for injection.
Librela 30 mg Solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml contains 5 mg bedinvetmab.
Each 1 ml contains 10 mg bedinvetmab.
Each 1 ml contains 15 mg bedinvetmab.
Each 1 ml contains 20 mg bedinvetmab.
Each 1 ml contains 30 mg bedinvetmab.

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 Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/20/261/001	5 mg 1 vial
EU/2/20/261/002	5 mg 2 vials
EU/2/20/261/003	5 mg 6 vials
EU/2/20/261/004	10 mg 1 vial
EU/2/20/261/005	10 mg 2 vials
EU/2/20/261/006	10 mg 6 vials
EU/2/20/261/007	15 mg 1 vial
EU/2/20/261/008	15 mg 2 vials
EU/2/20/261/009	15 mg 6 vials
EU/2/20/261/010	20 mg 1 vial
EU/2/20/261/011	20 mg 2 vials
EU/2/20/261/012	20 mg 6 vials
EU/2/20/261/013	30 mg 1 vial
EU/2/20/261/014	30 mg 2 vials
EU/2/20/261/015	30 mg 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**

Librela

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

bedinvetmab 5 mg/ml
bedinvetmab 10 mg/ml
bedinvetmab 15 mg/ml
bedinvetmab 20 mg/ml
bedinvetmab 30 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

Librela 5 mg solution for injection for dogs
Librela 10 mg solution for injection for dogs
Librela 15 mg solution for injection for dogs
Librela 20 mg solution for injection for dogs
Librela 30 mg solution for injection for dogs

2. Composition

Active substances:

Each vial of 1 ml contains 5 mg, 10 mg, 15 mg, 20 mg or 30 mg bedinvetmab*.

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

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

3. Target species

Dogs.

4. Indications for use

For the alleviation of pain associated with osteoarthritis 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 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.

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 they take (to prevent overexercise by some dogs).

Caution should be used when treating patients with the following pre-existing conditions: low amounts of red blood cells (immune-mediated haemolytic anaemia), lameness and swelling in multiple joints (immune-mediated polyarthritis), low amounts of platelets (thrombocytes) (immune-mediated thrombocytopenia).

Caution should be used when treating patients with pre-existing convulsion (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.

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:

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.

Overdose:

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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. 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, Vomiting. Incoordination (ataxia) ² . Increased need to urinate (polyuria), Urinary incontinence. Anorexia ³ , Lethargy, Increased thirst (polydipsia).
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction (anaphylaxis, facial swelling, itching (pruritus)) ⁴ . Low amounts of red blood cells (immune-mediated haemolytic anaemia); Joint pain, Lameness and Swelling in multiple joints (immune-mediated polyarthritis); Low amounts of platelets (thrombocytes) (immune-mediated thrombocytopenia). Weakness (paresis), Loss of movement (paralysis), convulsion (seizure).

¹Mild.

²Including incoordination due to reduced sensory function (proprioceptive ataxia).

³Often related to a transient reduced appetite.

⁴In 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.

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).

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 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.

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/2/20/261/001-015

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

{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 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
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infovet.cz@zoetis.com

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farmacovigilanza.italia@zoetis.com**Κύπρος**

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