

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 10 mg Solution for injection for dogs.
bedinvetmab

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml contains 10 mg bedinvetmab.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 x 1 ml

2 x 1 ml

6 x 1 ml

5. TARGET SPECIES



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Store in the original package.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5030

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL – 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Librela 10 mg Solution for injection for dogs
bedinvetmab



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

bedinvetmab 10 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. 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
bedinvetmab

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:

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.

4. INDICATION(S)

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. ADVERSE REACTIONS

Mild reactions at the injection site (e.g. swelling and heat) may uncommonly be observed.

Hypersensitivity-type reactions have been reported very rarely. In case of such reactions, appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.



8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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:

	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).

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

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.

Shelf life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

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.

Special precautions for use in animals:

None

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 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 Librela's administration, to reduce any potential impact on immunogenicity of the vaccine.

Overdose (symptoms, emergency procedures, antidotes):

No adverse reactions, except mild reactions at the injection site, were observed in a laboratory overdose study when Librela 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.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Clear glass Type I vials with fluorobutyl rubber stopper.

Secondary packaging: cardboard box.

Pack sizes:

Cardboard box with 1, 2 or 6 vials of 1 ml

Not all pack sizes may be marketed.

Approved 09 May 2022

