PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Librela 10 mg Solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains 10 mg bedinvetmab.

3. PACKAGE SIZE

1 x 1 ml
2 x 1 ml
6 x 1 ml

4. TARGET SPECIES

Dogs

5. INDICATION(S)

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5030

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Librela

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

bedinvetmab 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

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

6. ROUTE(S) OF ADMINISTRATION

SC

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Librela 10 mg solution for injection for dogs

2. COMPOSITION

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.

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 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 WARNING(S)

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).

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 Librela's 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 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.

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 (injection site swelling, injection site warmth)[1].
Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, vomiting (emesis), ataxia, Increased need to urinate (polyuria), urinary incontinence, anorexia, lethargy, increased thirst (polydipsia).
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (anaphylaxis, facial swelling, itching (pruritus))[2], low amounts of red blood cells and thrombocytes (immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia), seizure.

[1] Mild
[2] 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 or the local representative of 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-medicineproblem/animal-reacts-medicine e-mail: adverse.events@vmd.gov.uk

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

None.

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. 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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. 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 42058/5030

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.

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 reactions:

United Kingdom (Great Britain)
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034

Marketing authorisation holder and manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
Tél/Tel: +32 (0) 800 99 189

Република България
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Белгия
Тел: +359 888 51 30 30

Česká republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
CZ 150 00 Praha
Tel: +420 257 101 111

Danmark
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Tlf: +45 70 20 73 05
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Zoetis Belgium
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1930 Zaventem
Belsch
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Magyarország
Zoetis Hungary Kft.
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HU-1124 Budapest
Tel.: +36 1 224 5200

Malta
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Mdina Road, Zebbug ZBG 9016,
MT
Tel: +356 21 465 797

Nederland
Zoetis B.V.
Rivium Westlaan 74
NL-2909 LD Capelle aan den IJssel
Tel: +31 (0)10 714 0900

Eesti
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Mercuriusstraat 20
1930 Zaventem
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Tel: +370 610 05088

Ελλάδα
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Φραγκοκκλησιάς 7, Μαρούσι
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España
Zoetis Spain, S.L.
Parque Empresarial Vía Norte Edificio nº1,
c/ Quintanavides nº13
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France
Zoetis France
10 rue Raymond David
FR-92240 Malakoff
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Hrvatska
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Podružnica Zagreb za promidžbu
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ul. Postępu 17B
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17. OTHER INFORMATION

Gavin Hall

Approved: 03 December 2024