**VIAL LABEL**
**Main Panel**

[graphic?]

# BERANSA® 5 mg
**Bedinvetmab 5 mg/mL**

**1 mL – SC**

Solution for injection for dogs

[Label identifier]

**VIAL LABEL**
**Side Panel**

[Zoetis logo]

Lot:

EXP:

**RVM**; ACVM No. A11845
For animal treatment only

MINISTRY FOR PRIMARY INDUSTRIES
NEW ZEALAND
30/11/2021

**CARTON**
**Main Panel**

[graphic?]

**DANGER**
**KEEP OUT OF REACH OF CHILDREN**
**FOR ANIMAL TREATMENT ONLY**
**RESTRICTED VETERINARY MEDICINE**

# BERANSA® 5 mg
**Bedinvetmab 5 mg/mL**

**2 [1,6] x 1 mL - SC**

**Solution for injection for dogs**
For the alleviation of pain associated with osteoarthritis in dogs.

[Zoetis logo]

**CARTON**
**Rear Panel**

**READ THE ENCLOSED LEAFLET BEFORE USE**

**Restricted Veterinary Medicine**
Registered pursuant to the ACVM Act 1997, No. A11845
See www.foodsafety.govt.nz for registration conditions
Approved pursuant to the HSNO Act 1996, Approval No. HSR100757
See www.epa.govt.nz for approval conditions

Registered to:
**Zoetis New Zealand Limited**
8 Mahuhu Crescent, Auckland
Technical Services 0800 650 277
www.zoetis.co.nz



[Barcode]

**CARTON**
**Side Panel 1**

**STORAGE:** Store between 2°C to 8°C (Refrigerate. Do not freeze). Store in the original package. Protect from light.

**DISPOSAL:** Dispose of contents/container in the medical waste.

**CARTON**
**Side Panel 2**

Lot:

EXP:

[Label identifier]

**LEAFLET (Common)**

**DANGER**
**KEEP OUT OF REACH OF CHILDREN**
**FOR ANIMAL TREATMENT ONLY**
**RESTRICTED VETERINARY MEDICINE**

[graphic?]

# BERANSA® 5 mg

**Bedinvetmab 5 mg/mL**
Solution for injection for dogs

## DESCRIPTION

Bedinvetmab is a canine anti-Nerve Growth Factor (NGF) monoclonal antibody (mAb) expressed through recombinant techniques in CHO cells.

## INDICATIONS

For the alleviation of pain associated with osteoarthritis in dogs.

## DOSAGE AND ADMINISTRATION

The recommended dose is 0.5 – 1.0 mg/kg bodyweight, administered subcutaneously, 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 volumes ≤ 0.5 mL, use an adequate syringe size and dose to the nearest 0.1 mL.
For dogs between 5 and 60 kg administer the entire content of the vial (1 mL) according to the table below:

| **Bodyweight (kg)** | **BERANSA Strength (mg/mL) 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 – 120.0 | | | | | 2 vials |

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

**Overdose:** No adverse reactions were observed in laboratory overdose studies. Beransa was well tolerated at 1, 3, and 10 times the recommended maximum dose of 1 mg/kg in normal healthy dogs. In case of adverse clinical signs after an overdose, the dog should be treated symptomatically.

**CONTRAINDICATIONS**
Do not use in case 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.

**ADVERSE REACTIONS**
Like any other therapeutic protein, bedinvetmab may induce transient or persistent anti-drug antibodies. The induction of such antibodies may reduce bedinvetmab's efficacy. As with any immunological product, in rare cases hypersensitivity reactions may occur. If such a reaction occurs, appropriate symptomatic treatment should be administered without delay.
Mild injection site reactions may uncommonly be observed.

**PREGNANCY AND LACTATION**
The role of Nerve Growth Factor (NGF) in foetal nervous system development is well established, therefore do not use in pregnant or lactating animals.

**INTERACTIONS**
No drug interactions were observed in field studies where bedinvetmab was administered concomitantly with veterinary medicinal products such as parasiticides, nutritional supplements, 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 bedinvetmab, the vaccine(s) should be administered at a different site to that of bedinvetmab administration.

In a laboratory study over a 2-week period, bedinvetmab had no adverse effect when co-administered with a non-steroidal anti-inflammatory product (Carprofen).

There are no data investigating the safety of concurrent long-term use of NSAIDs and bedinvetmab in dogs.

In clinical trials in humans, rapidly progressive osteoarthritis has been reported in a small number of patients receiving high-dose humanized anti-NGF monoclonal antibody therapy. The incidence of these events increased in human patients receiving long-term (>90 days) non-steroidal anti-inflammatory drugs (NSAIDs) concomitantly with an anti-NGF monoclonal antibody. In patients receiving intermittent concomitant treatment with NSAID (fewer than 90 days per year), the incidence of rapidly progressive osteoarthritis was not increased.

Rapidly progressive osteoarthritis is not a recognised condition in dogs.

## HANDLING PRECAUTIONS

DANGER.
May damage fertility or the unborn child. May cause harm to breast-fed children.
Avoid contact during pregnancy and while nursing. Do not eat, drink or smoke when using this product. Wear protective gloves. Wash hands thoroughly after handling. If exposed or concerned, get medical advice.
Dispose of contents/container in the medical waste.

Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection.

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 or needle stick injuries.**

## FIRST AID
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

## STORAGE
Store between 2°C to 8°C (Refrigerate. Do not freeze). Store in the original package. Protect from light. Use immediately after opening.

## DISPOSAL
Dispose of contents/container in the medical waste.

## GENERAL INFORMATION
BERANSA (bedinvetmab) is a canine therapeutic monoclonal antibody (mAb) that targets Nerve Growth Factor (NGF). The inhibition of NGF-mediated cell signalling has been demonstrated to provide relief from pain associated with osteoarthritis (OA).
In controlled field studies lasting up to 3 months, treatment of dogs with OA was demonstrated to have a favourable effect on the reduction of pain assessed by the Canine Brief Pain Inventory (CBPI). CBPI is an assessment of an individual dog's response to pain treatment as assessed by pain severity, interference of pain with the dog's typical activities and quality of life. Treatment with bedinvetmab has demonstrated a positive effect on all three components of the CBPI. BERANSA demonstrated an onset of efficacy by the first assessed time point at 7 days post administration. In an uncontrolled follow-up field study lasting up to nine months on-going analgesic efficacy was observed.

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 Cmax increased nearly in proportion to dose and steady state was achieved after approximately 2 doses. In a laboratory pharmacokinetic study at the label dose (0.5-1.0 mg/kg), peak serum drug levels were observed at 2-7 days after subcutaneous dosing, the bioavailability relative to an intravenous dose was approximately 84%, and the elimination half-life was approximately 13 days.

In a field effectiveness study at the label dose in dogs with osteoarthritis, the half-life averaged 19 ± 8 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.

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[Label identifier]