B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

MAROPITANT Bioveta 10 mg/ml solution for injection for dogs and cats

2. Composition

Each ml contains:

Active substance:
Maropitant (as Maropitant citrate monohydrate) 10 mg

Excipients:
Methyl parahydroxybenzoate (E 218) 2.20 mg
Propyl parahydroxybenzoate 0.22 mg

A clear, colourless to light yellow solution, free of visible particles.

3. Target species

Dogs and cats.

4. Indications for use

Dogs:
• For the treatment and prevention of nausea induced by chemotherapy.
• For the prevention of vomiting except that induced by motion sickness.
• For the treatment of vomiting, in combination with other supportive measures.
• For the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the μ-opiate receptor agonist morphine

Cats:
• For the prevention of vomiting and the reduction of nausea, except that induced by motion sickness.
• For the treatment of vomiting, in combination with other supportive measures.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Vomiting can be associated with serious, severely debilitating conditions including gastrointestinal obstructions. Therefore, appropriate diagnostic evaluations should be employed.
Good veterinary practice indicates that antiemetics should be used in conjunction with other veterinary and supportive measures such as dietary control and fluid replacement therapy while addressing the underlying causes of the vomiting.
The use of the veterinary medicinal product against vomiting due to motion sickness is not recommended.

Dogs:
Although maropitant has been demonstrated to be effective in both the treatment and prevention of emesis induced by chemotherapy, it was found more efficacious if used preventively. Therefore, it is recommended to administer the antiemetic prior to administration of the chemotherapeutic agent.

Cats:
The efficacy of maropitant in reduction of nausea was demonstrated in studies using a model (xylazine-induced nausea).

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been established in dogs less than 8 weeks of age, or in cats less than 16 weeks of age, and in pregnant or lactating dogs and cats. Use only according to the benefit-risk assessment by the responsible veterinarian.
Maropitant is metabolised in the liver and therefore should be used with caution in patients with hepatic disease. As maropitant is accumulated in the body during a 14-day treatment period due to metabolic saturation, careful monitoring of liver function and any adverse events should be implemented during long term treatment.
Maropitant has affinity to Ca- and K-ion channels, therefore the veterinary medicinal product should be used with caution in animals suffering from or with predisposition for cardiac diseases. Increases of approximately 10% in the QT interval of the ECG were observed in a study on healthy beagle dogs administered 8 mg/kg orally; however, such an increase is unlikely to be of clinical significance.
Due to the frequent occurrence of transient pain during subcutaneous injection, appropriate animal restraining measures may have to be applied. Injecting the product at refrigerated temperature may reduce pain at injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Maropitant is a neurokinin-1 (NK1) receptor antagonist that acts in the central nervous system. The veterinary medicinal product may therefore cause nausea, dizziness and drowsiness in case of accidental self-injection. If accidental self-injection occurs, seek medical advice immediately and show the package leaflet or the label to the physician.
The veterinary medicinal product may cause skin sensitisation and local irritation. Skin contact should therefore be avoided. In case of accidental exposure, wash affected skin area with plenty of water.
People with known hypersensitivity to maropitant or to any of the excipients should administer the veterinary medicinal product with caution. If you develop symptoms such as a skin rash after accidental exposure, seek medical advice and show the package leaflet or the label to the physician.
The veterinary medicinal product may cause eye irritation. Eye contact should be avoided. In case of accidental eye exposure, flush the eyes with plenty of water and seek medical attention.
Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Veterinary medicinal product should not be used concomitantly with Ca-channel antagonists as maropitant has affinity to Ca-channels.
Maropitant is highly bound to plasma proteins and may compete with other highly bound medicines.

Overdose:
Apart from transient reactions at the injection site following subcutaneous administration, maropitant was well tolerated in dogs and young cats injected daily with up to 5 mg/kg (5 times the recommended dose) for 15 consecutive days (3-times the recommended duration of administration). No data have been presented on overdoses in adult cats.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dog and cat:

Very common (>1 animal / 10 animals treated):	Injection site pain[1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membranes). Lethargy Neurological disorder (ataxia, convulsion, seizure, muscle tremor)

[1] in cats – moderate to severe (in approximately one third of cats) when injected subcutaneously
[2] in dogs – when injected subcutaneously

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:

8. Dosage for each species, routes and method of administration

Subcutaneous or intravenous use in dogs and cats.

The veterinary medicinal product should be injected once daily, at a dose of 1 mg maropitant/kg bodyweight (1 ml veterinary medicinal product/10 kg bodyweight) for up to 5 consecutive days. Intravenous administration of the veterinary medicinal product be given as a single bolus without mixing the product with any other fluids.

9. Advice on correct administration

To prevent vomiting, the veterinary medicinal product should be administered more than 1 hour in advance. The effect duration is approximately 24 h and therefore the veterinary medicinal product can be administered the evening before administration of a substance that may induce vomiting, e.g. chemotherapy.
As the pharmacokinetic variation is large and maropitant accumulates in the body after once daily repeated administration, lower doses than recommended might be sufficient in some individuals and when repeating the dose.
The stopper may be punctured up to 20 times.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is 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: 28 days.

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

Cardboard box with 1 vial of 10 ml.

15. Date on which the package leaflet was last revised

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 reactions:
Bioveta, a. s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic
Tel: + 420 517 318 911
E-mail: reklamace@bioveta.cz

<Local representatives< and contact details to report suspected adverse reactions>:>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information