ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevomax 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Maropitant 10 mg

Excipients:
Benzyl alcohol (E1519) 11.1 mg

3. PACKAGE SIZE

10 ml
20 ml
25 ml
50 ml

4. TARGET SPECIES

Dogs, cats.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous or intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {month/year}
Once broached use within 56 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 50406/5002

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. Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevomax

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 56 days.

5. ROUTE(S) OF ADMINISTRATION

For SC and IV use.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevomax 10 mg/ml solution for injection for dogs and cats

2. COMPOSITION

1 ml contains:

Active substance:
Maropitant 10 mg

Excipients:
Benzyl alcohol (E1519) 11.1 mg

A clear, colourless to light yellow solution.

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

None.

6. SPECIAL WARNINGS

Special warnings:
Vomiting can be associated with serious, severely debilitating conditions and the cause should be investigated. Products such as Prevomax should be used in conjunction with other supportive measures such as dietary control and fluid replacement therapy.

Maropitant is metabolised in the liver and therefore should be used with caution in dogs and cats with liver disease. Prevomax should be used with caution in animals suffering from or with predisposition for heart diseases.

The use of Prevomax solution for injection 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 veterinary medicinal product prior to administration of the chemotherapeutic agent.

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

Special precautions for safe use in the target species:
The safety of maropitant has not been established in dogs less than 8 weeks of age, or in cats less than 16 weeks of age, or in pregnant or lactating dogs and cats. The responsible veterinarian should make a benefit-risk assessment before using the veterinary medicinal product in dogs less than 8 weeks of age, or in cats less than 16 weeks of age, or in pregnant or lactating bitches and cats.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to maropitant should administer the veterinary medicinal product with caution.
Wash hands after use. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Maropitant has been shown to be a potential eye irritant, and in the case of accidental eye exposure, flush the eyes with plenty of water and seek medical attention.

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian, because conclusive reproductive toxicity studies have not been conducted in any animal species.

Interaction with other medicinal products and other forms of interaction:
The 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 (symptoms, emergency procedures, antidotes):
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:
Prevomax must not be mixed with other veterinary medicinal products in the same syringe as its compatibility with other products has not been tested.

7. ADVERSE EVENTS

Target species: Dog, cat

Very common (>1 animal / 10 animals treated):	Injection site pain[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reactions (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membranes) Lethargy Ataxia, Convulsion, Seizure, Muscle tremor
Undetermined frequency	Injection site pain[b]

[a] in cats - moderate to severe (in approximately one third of cats) when injected subcutaneously.
[b] 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 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

For subcutaneous or intravenous use in dogs and cats.

Prevomax solution for injection should be injected subcutaneously or intravenously, once daily, at a dose of 1 mg of maropitant/kg bodyweight (1 ml/10 kg bodyweight). Treatment may be repeated for up to five consecutive days. Intravenous administration of Prevomax should be given as a single bolus without mixing the product with any other fluids.

9. ADVICE ON CORRECT ADMINISTRATION

To prevent vomiting, Prevomax solution for injection should be administered more than 1 hour in advance. The duration of effect is approximately 24 h and therefore treatment can be given the night before administration of an agent that may cause emesis, e.g. chemotherapy.

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.

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.

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the vial: 56 days.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/5002

Amber glass type I vial closed with a coated bromobutyl rubber stopper and aluminium cap in a cardboard box.
Pack sizes of 1 vial of 10 ml, 20 ml, 25 ml or 50 ml.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
Tel.: +31 348 563434

Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ
Raamsdonksveer The
Netherlands

Eurovet Animal Health
B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

17. OTHER INFORMATION

POM-V. Veterinary medicinal product subject to prescription.

For animal treatment only.

Approved 17 November 2023