A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Maropitant 10 mg/ml

3. PACKAGE SIZE

10 ml
20 ml
25 ml
50 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use, intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}
Once broached use within 56 days

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

14. MARKETING AUTHORISATION NUMBER(S)

Vm 20916/5012

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

Glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Maropitant 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}
Once broached use within 56 days.
Once broached use by:

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

10 ml
20 ml
25 ml
50 ml

6. ROUTE(S) OF ADMINISTRATION

SC, IV

7. WITHDRAWAL PERIOD

8. 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

Vetemex 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 WARNING(S)

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 veterinary medicinal product 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 maropitant 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.

The veterinary medicinal product should be used with caution in animals suffering from or with predisposition for cardiac diseases as maropitant has affinity to Ca- and K-ion channels. 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 irritation. Skin contact should therefore be avoided. In case of accidental exposure, wash affected skin area with plenty of water.
The veterinary medicinal product may cause skin sensitization. People with known hypersensitivity to maropitant and/or benzyl alcohol should avoid contact with the veterinary medicinal product. If you develop symptoms such as a rash after accidental exposure, seek medical advice and show the physician this warning.

The veterinary medicinal product may cause eye irritation. Eye contact should be avoided. In case of accidental exposure, flush eyes with plenty of water and seek medical attention immediately.

Wash hands after use.

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:
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.

Special restrictions for use and special conditions for use:
Information from SPC section 3.11 appropriate to the package leaflet

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

For Animal Treatment Only

Keep out of sight and reach of children

7. ADVERSE EVENTS

Dogs:

Frequency	**Adverse event**
Common (1 to 10 animals / 100 animals treated):	Injection site pain*
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reactions (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membranes) Neurological disorders such as ataxia, convulsion/seizure or muscle tremor; lethargy

* when injected subcutaneously

Cats:

Frequency	Adverse event
Very common (>1 animal / 10 animals treated)	Injection site pain*
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reactions (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membranes) Neurological disorders such as ataxia, convulsion/seizure or muscle tremor; lethargy

* when injected subcutaneously: moderate to severe response to injection (in approximately one third of cats)

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: UK: https://www.gov.uk/report-veterinary-medicine-problem

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For subcutaneous or intravenous use in dogs and cats.

The veterinary medicinal product 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) for up to 5 consecutive days. Intravenous administration of the veterinary medicinal product should be given as a single bolus without mixing the product with any other fluids.

9. ADVISE ON CORRECT ADMINISTRATION

To prevent vomiting, the veterinary medicinal product 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.

For administration by subcutaneous injection, see also “Special precautions for safe use in the target species: special precautions for use in animals” (section on Special Warnings).
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 PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton.
Shelf life after first opening the vial: 56 days.
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.
Do not use this veterinary medicinal product after the expiry date which is stated on the label of the vial after EXP. The expiry date refers to the last day of that month.

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 requirement.'

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V ('To be supplied only on veterinary prescription')

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 20916/5012

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

November 2022

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

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

Local representatives and contact details to report suspected adverse reactions:
Virbac Ltd
Suffolk
IP30 9UP
UK
Tel: +44 (0)-1359 243243

17. OTHER INFORMATION

Vm 20916/5012

POM-V To be supplied only on veterinary prescription

Distributor:
Virbac Ltd - Suffolk IP30 9UP - UK

Approved 18 July 2023