PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard box 10 ml, 5 x 10 ml, 25 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Maropitant	10 mg/ml
Excipients:	
n-Butanol	22 mg/ml

3. PACKAGE SIZE

10 ml
25 ml
50 ml
5 x 10 ml

4. TARGET SPECIES

Dogs, cats

5. INDICATION(S)

-

6. ROUTES OF ADMINISTRATION

For subcutaneous or intravenous use.

7. WITHDRAWAL PERIODS

-

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 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

VetViva Richter

14. MARKETING AUTHORISATION NUMBERS

Vm 57446/5004

15. BATCH NUMBER

Lot:

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

Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. TARGET SPECIES

4. ROUTES OF ADMINISTRATION

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

7. SPECIAL STORAGE PRECAUTIONS

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

10. PACKAGE SIZE

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

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

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

15. MARKETING AUTHORISATION NUMBER(S)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {10 ml, 25 ml, 50 ml amber glass vial closed with a chlorobutyl or bromobutyl rubber stopper and aluminium cap }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vominil

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Maropitant 10 mg/ml

3. BATCH NUMBER

Lot:

4. EXPIRY DATE

Exp:

Once broached use by …

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

10 ml

25 ml

50 ml

6. ROUTE(S) OF ADMINISTRATION

For subcutaneous or intravenous use.

7. WITHDRAWAL PERIOD

-

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

3. BATCH NUMBER

4. EXPIRY DATE

5. NAME OF THE MARKETING AUTHORISATION HOLDER

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT/SOLVENT LABEL

1. NAME OF THE DILUENT/SOLVENT

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3. ROUTES OF ADMINISTRATION

4. STORAGE CONDITIONS

5. BATCH NUMBER

6. EXPIRY DATE

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

8. NAME OF THE MARKETING AUTHORISATION HOLDER

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vominil 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:
n-Butanol 22 mg

Clear, colourless to almost colourless solution.

3. TARGET SPECIES

Dogs, 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.

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:

This product may cause skin sensitisation. People with known hypersensitivity to maropitant should administer the veterinary medicinal product with caution. Wash the exposed skin immediately after exposure with large amounts of water. If you develop symptoms such as a rash after accidental exposure, seek medical advice and show the physician this warning.
This veterinary medicinal product may be irritant to the eyes. Avoid eye contact. In case of accidental contact of the product with eyes rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.
Maropitant is a neurokinin-1 (NK1) receptor antagonist that acts in the central nervous system. Accidental self-injection or ingestion may result in nausea, dizziness and somnolence. Care should be taken to avoid accidental self-injection. In case of accidental oral intake or self-injection seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Use only accordingly 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, the active substance, 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 is available on overdoses in adult cats.

Special restrictions for use and special conditions for use:
Not applicable.

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.

7. ADVERSE EVENTS

Dogs, cats:

Very common (>1 animal / 10 animals treated):	Injection site pain*
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction, allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membrane; Lethargy; Neurological disorders (e.g. ataxia, convulsion/ seizure, muscle tremor)

*May occur when injected subcutaneously. In approximately one third of cats moderate to severe response to injection is observed.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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, ROUTE(S) AND METHOD OF ADMINISTRATION

For subcutaneous or intravenous use.

The veterinary medicinal product should be injected subcutaneously or intravenously, once daily, at a dose of 1 mg/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 veterinary medicinal product with any other fluids.

To ensure a correct dosage, body weight should be determined as accurately as possible.

9. ADVICE ON CORRECT ADMINISTRATION

To prevent vomiting, the veterinary medicinal product 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.
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.
For administration by subcutaneous injection, see also ‘special precautions for safe use in the target species’.

10. WITHDRAWAL PERIOD(S)

Not appliable.

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 label and carton after Exp. The expiry date refers to the last day of that month.

Once the vial is broached, using the shelf-life after first opening, calculate the discard date and record in the space provided.
Shelf life after first opening the immediate packaging: 28 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. These measures should help to protect the environment.

Medicines should not be disposed of via wastewater or household waste. Dispose of waste material in accordance with local requirements. Ask your veterinay surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment. 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.

FOR GB/NI ONLY: 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. 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 57446/5004

Pack sizes:

1 x 10 ml, 1 x 25 ml, 1 x 50 ml, 5 x 10 ml

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 2023

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

17. OTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {NATURE/TYPE}

[This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. COMPOSITION

3. PACKAGE SIZE

4. TARGET SPECIES

5. INDICATIONS FOR USE

6. CONTRAINDICATIONS

7. SPECIAL WARNINGS

8. ADVERSE REACTIONS

9. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIOD

12. SPECIAL STORAGE PRECAUTIONS

13. SPECIAL PRECAUTIONS FOR DISPOSAL

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

16. DATE ON WHICH THE LABEL WAS LAST REVISED

17. CONTACT DETAILS

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

20. EXPIRY DATE

21. BATCH NUMBER

22. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Approved 06 October 2023