Vominil

10 mg/ml

VetViva® Richter

PACKAGE INSERT

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:

Betadex Sulfobutyl Ether Sodium	63mg
n-Butanol	22 mg

Clear, colourless to almost colourless solution for injection.

3. Target species
Dogs, cats

4. Indications for use
Dogs
- For the treatment and prevention of nausea induced by chemo-therapy.
- For the prevention of vomiting except that induced by motion sickness.
- For the treatment of vomiting, in combination with other sup-portive 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 sup-portive 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 con-ditions including gastrointestinal obstructions; therefore, appro-priate diagnostic evaluations should be employed.

Good veterinary practice indicates that antiemetics should be used in conjunction with other veterinary and supportive meas-ures 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 chemo-therapy, it was found more efficacious if used preventively. There-fore, it is recommended to administer the antiemetic prior to administration of the chemotherapeutic agent.

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

Special precautions for safe use in animals:
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 subcu-taneous injection, appropriate animal restraining measures may have to be applied. Injecting the veterinary medicinal product at refrigerated temperature may reduce pain at injection.

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. In laboratory studies, maropitant has been shown to be a potential eye irritant. In the case of accidental eye exposure, flush the eyes with plenty of water and seek medical attention.

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

Interaction with other medicinal products and other forms of inter-action:
The veterinary medicinal product should not be used concomi-tantly 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 rec-ommended duration of administration). No data is available 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 prod-ucts 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. Neurologi-cal disorders (e.g. ataxia, convulsion/seizure, muscle tremor)

*May occur when injected subcutaneously. A moderate to severe response can be observed in approximately one third of cats.

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, routes and method of admin-istration
For subcutaneous or intravenous use.

The veterinary medicinal product should be injected subcutane-ously 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.

The rubber stopper may be safely punctured up to 100 times.

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 accumu-lates 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 pre-cautions for safe use in the target species'.

10. Withdrawal periods
Not applicable.

11. Pharmacodynamics
Vomiting is a complex process coordinated centrally by the emetic centre. This centre consists of several brainstem nuclei (area pos-trema, nucleus tractus solitarius, dorsal motor nucleus of the vagus) that receive and integrate sensory stimuli from central and peripheral sources and chemical stimuli from the circulation and the cerebro-spinal fluid.

Maropitant is a neurokinin 1 (NK1) receptor antagonist, which acts by inhibiting the binding of substance P, a neuropeptide of the tachykinin family. Substance P is found in significant concentra-tions in the nuclei comprising the emetic centre and is considered the key neurotransmitter involved in vomiting. By inhibiting the binding of substance P within the emetic centre, maropitant is effective against neural and humoral (central and peripheral) causes of vomiting.

A variety of *in vitro* assays have demonstrated that maropitant binds selectively at the NK1 receptor with dose-dependent func-tional antagonism of substance P activity.

Maropitant is effective against vomiting. The anti-emetic efficacy of maropitant against central and peripheral emetics was demon-strated in experimental studies including apomorphine, cisplatin and syrup of ipecac (dogs) and xylazine (cats).

Signs of nausea in dogs including excessive salivation and lethargy might remain after treatment.

Date of Revision 1st July 2026

Design Information	
Size	210 x 297 mm (DIN A4)
Text column 1	9 pt
Text column 2	9 pt
Packaging No.	00000/A
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12.
Pharmacokinetics
Dogs
The pharmacokinetic profile of maropitant when administered as a single subcutaneous dose of 1 mg/kg body weight to dogs was characterised by a maximum concentration (C^{max}) in plasma of approximately 92 ng/ml; this was achieved within 0.75 hours post-dosing (T^{max}). Peak concentrations were followed by a decline in systemic exposure with an apparent elimination half-life ($t^{1/2}$) of 8.84 hours. Following a single intravenous dose at 1 mg/kg the initial plasma concentration was 363 ng/ml. The volume of distri-bution at steady-state (Vss) was 9.3 l/kg and systemic clearance was 1.5 l/h/kg. The elimination $t^{1/2}$ following intravenous dosing was approximately 5.8 h.

During clinical studies maropitant plasma levels conferred efficacy from 1 hour after administration. The bioavailability of maropitant after subcutaneous administration in dogs was 90.7%. Maropitant displays linear kinetics when administered subcutaneously within the 0.5–2 mg/kg dose range.

Following repeated subcutaneous administration of once-daily doses of 1 mg/kg bodyweight for five consecutive days, accumu-lation was 146%. Maropitant undergoes cytochrome P450 (CYP) metabolism in the liver. CYP2D15 and CYP3A12 were identified as the canine isoforms involved in the hepatic biotransformation of maropitant.

Renal clearance is a minor route of elimination, with less than 1% of a 1 mg/kg subcutaneous dose appearing in the urine as either maropitant or its major metabolite. Plasma protein binding of maropitant in dogs is more than 99%.

Cats
The pharmacokinetic profile of maropitant when administered as a single subcutaneous dose of 1 mg/kg body weight to cats was characterised by a maximum concentration (C^{max}) in plasma of approximately 165 ng/ml; this was achieved on average 0.32 hours (19 min) post-dosing (T^{max}). Peak concentrations were fol-lowed by a decline in systemic exposure with an apparent elimi-nation half-life ($t^{1/2}$) of 16.8 hours. Following a single intravenous dose at 1 mg/kg the initial plasma concentration was 1040 ng/ml. The volume of distribution at steady-state (Vss) was 2.3 l/kg and systemic clearance was 0.51 l/h/kg. The elimination $t^{1/2}$ following intravenous dosing was approximately 4.9 h. There appears to be an age-related effect on the pharmacokinetics of maropitant in cats with kittens having higher clearance than adults.

During clinical studies maropitant plasma levels conferred efficacy from 1 hour after administration.

The bioavailability of maropitant after subcutaneous administra-tion in cats was 91.3%. Maropitant displays linear kinetics when administered subcutaneously within the 0.25–3 mg/kg dose range.

Following repeated subcutaneous administration of once-daily doses of 1 mg/kg bodyweight for five consecutive days, accumu-lation was 250%. Maropitant undergoes cytochrome P450 (CYP) metabolism in the liver. CYP1A and CYP3A-related enzymes were identified as the feline isoforms involved in the hepatic biotrans-formation of maropitant.

Renal and faecal clearances are minor routes of elimination for maropitant, with less than 1% of a 1 mg/kg subcutaneous dose appearing in the urine or faeces as maropitant. For the major metabolite 10.4% of the maropitant dose was recovered in urine and 9.3% in faeces. Plasma protein binding of maropitant in cats was estimated to be 99.1%.

13. Special storage precautions
Keep out of the sight and reach of children.

Store below 25°C (air conditioning).
Keep the container in the outer carton.

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.

Shelf life after first opening the immediate packaging: 28 days

14. Special precautions for disposal
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal.
Medicines should not be disposed of via wastewater or household waste.
Ask you veterinary surgeon or pharmacist how to dispose of medicines no longer required.

15. Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

16. Marketing authorisation numbers and pack sizes
Pack sizes:
Cardboard box with 1 vial (25mL)

Date on which the package leaflet was last revised
1st July 2026

18. Contact details
Manufacturer:
VetViva Richter GmbH
Durisolstrasse 14
4600 Wels
Austria

Marketing authorisation holder, local representatives and contact details to report suspected adverse reactions:
Gladron Chemicals Sdn. Bhd.
No. 7 Jalan TP 7,
Taman Perindustrian UEP,
40400 Shah Alam Selangor,
Malaysia.

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

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