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619089 **PACKAGE LEAFLET**

Prevomax 10 mg/ml

Solution for injection for dogs and cats

Name of the veterinary medicinal product: Prevomax 10 mg/ml solution for injection for dogs and cats
Composition: 1 ml contains: **Active substance:** Maropitant 10 mg; **Excipients:** Benzyl alcohol (E1519) 11.1 mg
A clear, colourless to light yellow solution.
Target species: Dogs and cats.
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.
Contraindications: None.
Warnings and precautions: 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 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, 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: 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.
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.
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).

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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.
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.
Withdrawal periods: Not applicable.
Pharmacodynamics: Vomiting is a complex process coordinated centrally by the emetic centre. This centre consists of several brainstem nuclei (area postrema, 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 concentrations 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 functional antagonism of substance P activity.Maropitant is effective against vomiting. The anti-emetic efficacy of maropitant against central and peripheral emetics was demonstrated 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.
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 (Cmax) in plasma of approximately 92 ng/ml; this was achieved within 0.75 hours post-dosing (Tmax). Peak concentrations were followed by a decline in systemic exposure with an apparent elimination half-life (t1/2) of 8.84 hours. Following a single intravenous dose at 1 mg/kg the initial plasma concentration was 363 ng/ml. The volume of distribution at steady-state (Vss) was 9.3 l/kg and systemic clearance was 1.5 l/h/kg. The elimination t1/2 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, accumulation 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 (Cmax) in plasma of approximately 165 ng/ml; this was achieved on average 0.32 hours (19 min) post-dosing (Tmax). Peak concentrations were followed by a decline in systemic exposure with an apparent elimination half-life (t1/2) 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 t1/2 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 administration 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, accumulation 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 biotransformation 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%.
Environmental properties: Keep out of the sight and reach of children / Jauhi ubat daripada kanak-kanak. Do not freeze. Store below 30°C. 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.
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.
Classification of veterinary medicinal products: Veterinary medicinal product subject to prescription.
Marketing authorisation number and pack sizes: Marketing authorization number: MAL: number/0/00/000/000
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.
Contact details: Marketing authorisation holder and contact details to report suspected adverse reactions: My Vet Care Sdn. Bhd., A-G-3A, Red Ruby Shop Apartment, Jalan Indah 2/4, Taman Universiti Indah, 43300 Seri Kembangan, Selangor, Malaysia
Manufacturer responsible for batch release: Eurovet Animal Health B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands
Date on which the package insert was last approved: DD-MM-YYYY
Other information: POM-V Veterinary medicinal product subject to prescription. For animal treatment only.

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Product: ..... **Prevomax - 10 mg/ml - MY - Leaflet**

Dimensions:..... 148 mm x 210 mm
Primary brand name font size: 23pt
Primary brand description font size:.....13.8pt
Body text font size: 8pt
Item code: 619089
Pharmacode: ..... N/A

Proof:	Date:	Proof:	Date:
2.1 (NH)	10-09-2024		
2.2 (NH)	11-09-2024		
2.3 (EM)	12-05-2025		
2.4 (EM)	13-05-2025		

Pantone reference guide
Colours to be printed:
BLACK

Do not print
CUTTER GUIDE

STYLE DEVIATIONS

REGULATORY AUTHORITIES' REQUESTS

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