



MAROVET 10MG/ML INJECTION

Description and Composition

MAROVET 10MG/ML INJECTION is a colorless clear solution. Each ml contains 10mg Maropitant (as citrate) as its active ingredient and 11.1mg Benzyl Alcohol as its preservative.

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 nerve) 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 1mg / kg body weight to dogs was characterised by a maximum concentration (C_{max}) in plasma of approximately 92ng / 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 1mg / kg the initial plasma concentration was 363ng / ml. The volume of distribution at steady state (V_{ss}) was 9.3l / kg and systemic clearance was 1.5l / h / kg. The elimination t_{1/2} following intravenous dosing was approximately 5.8 h.

Cats

The pharmacokinetic profile of maropitant when administered as a single subcutaneous dose of 1mg / kg body weight to cats was characterised by a maximum concentration (C_{max}) in plasma of approximately 165ng / ml; this was achieved on average 0.32 hours (19 min) post-dosing (T_{max}). Peak concentrations were followed by a decline in systemic exposure with an apparent elimination half-life (t_{1/2}) of 16.8 hours. Following a single intravenous dose at 1mg / kg the initial plasma concentration was 1040ng / ml. The volume of distribution at steady state (V_{ss}) was 2.3l / kg and systemic clearance was 0.51l / 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.

Indication

Dogs: For treatment and prevention of nausea induced by chemotherapy; prevention of vomiting except that induced by motion sickness; treatment of vomiting, in combination with other supportive measures; and prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the μ -opiate receptor agonist morphine.

Cats: For prevention of vomiting and the reduction of nausea, except that induced by motion sickness, and treatment of vomiting, in combination with other supportive measures.

Recommended Dose

For subcutaneous or intravenous use in dogs and cats.

The product should be injected subcutaneously or intravenously, once daily, at a dose of 1mg / kg body weight (1ml / 10kg body weight) for up to 5 consecutive days. Intravenous administration should be given as a single bolus without mixing the product with any other fluids.

To prevent vomiting, the product should be administered more than 1 hour in advance. The effect duration 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.

Route of Administration

To be given by subcutaneous or intravenous injection in dogs and cats.

Contraindications

None.

Warning and Precautions

Special warnings for each target species

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 this product against vomiting due to motion sickness is not recommended.

Dogs: Although the product 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 the product in reduction of nausea was demonstrated in studies using a model (xylazine-induced nausea).

Special precautions for use

Special precautions for 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 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.

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.

Interactions with Other Medicaments

The 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.

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.

Side Effects

Dogs and cats:

Very common (>1 animal / 10 animals treated):	Injection site pain ^{1,2}
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction (e.g. allergic oedema, urticaria, erythema, collapse NOS, dyspnoea, pale mucous membranes) Lethargy Neurological disorder (e.g. ataxia, convulsion, seizure, muscle tremor)

¹ When injected subcutaneously.

² 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. Reports should be sent, preferably via a veterinarian, to either the marketing authorization holder or its local representative or the national competent authority via the national reporting system.

Symptoms and Treatment of Overdose

Apart from transient reactions at the injection site following subcutaneous administration, the product was well tolerated in dogs and young cats injected daily with up to 5mg / 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.

Storage Condition

Store below 30°C.

Shelf life

3 years.

Discard 2 months after first opening.

Packing

20ml, 50ml, 100ml, 250ml

Manufacturer & Product Registration Holder

Range Pharma Sdn Bhd

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