

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vomend 5 mg/ml solution for injection for dogs and cats
(Austria, Germany, Italy, Luxembourg, Portugal, The Netherlands, United Kingdom)

VOMEND ANTI-EMETICUM solution for injection
(France)

VOMEND ANTI-EMETICUM 5 mg/ml solution for injection for dogs and cats
(Belgium, Spain)

Vomend Vet. 5 mg/ml solution for injection for dogs and cats
(Finland, Sweden)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Metoclopramide (as hydrochloride monohydrate)	4.457 mg
equivalent to metoclopramide hydrochloride	5 mg

Excipients:

Benzyl alcohol (E1519)	18 mg
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For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Symptomatic treatment of vomiting and reduced gastro-intestinal motility associated with gastritis, pyloric spasm, chronic nephritis and digestive intolerance to some drugs.

4.3 Contraindications

Do not use in cases of gastro-intestinal perforation or obstruction.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The dosage must be adapted in animals with renal or hepatic insufficiency (due to an increase in the risk of side effects). Avoid administration to animals with epilepsy. The dosage should be carefully observed, especially in cats and small breed dogs.

Following prolonged vomiting, consideration should be given to fluid and electrolyte replacement therapy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after administration to the animal.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

In case of accidental exposure by spillage onto the skin or eyes, wash immediately with abundant water. If adverse effects appear, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In some very rare cases, extrapyramidal effects (agitation, ataxia, abnormal positions and/or movements, prostration, tremors and aggression, vocalisation) have been observed after treatment of dogs and cats.

The observed effects are transient and disappear when treatment is stopped.

In very rare cases, allergic reactions may occur.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in laboratory animals have not produced any evidence of a teratogenic or foetotoxic effects. However, studies on laboratory animals are limited and the safety of the active substance has not been evaluated in the target species. The use of the product during pregnancy and lactation must be made according to the benefit/risk assessment carried out by the veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

In cases of gastritis, avoid the co-administration of anticholinergic drugs (atropine) as they may counteract the effects of metoclopramide on gastrointestinal motility.

In cases of simultaneous diarrhoea, there is no contra-indication to the use of anticholinergic drugs.

Concurrent use of metoclopramide with neuroleptics derivated from phenothiazine (acepromazine) and butyrophenones increases the risk of extrapyramidal effects (see section 4.6).

Metoclopramide can potentiate the action of central nervous system depressants. If used concurrently, it is advised to use the lowest dosage of metoclopramide to avoid excessive sedation.

4.9 Amounts to be administered and administration route

Intramuscular or subcutaneous use.

0.5 mg metoclopramide hydrochloride per kg BW, if necessary repeated every 6-8 hours.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Most of the clinical signs reported after an overdosage are well known extrapyramidal side effects (see section 4.6).

In the absence of a specific antidote, it is recommended to offer a calm environment to the animal until extrapyramidal side effects disappear.

Metoclopramide being rapidly metabolised and eliminated, side effects generally disappear quickly.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: propulsives.
ATC Vet Code : QA03FA01

5.1 Pharmacodynamic properties

Metoclopramide is an original orthopramide molecule.

The anti-emetic action of metoclopramide is mainly due to its antagonist activity at D2 receptors in the central nervous system, preventing nausea and vomiting triggered by most stimuli.

The prokinetic effect on the gastro-duodenal transit (increase in intensity and rhythm of stomach contractions and opening of the pylorus) is mediated by muscarinic activity, D2 receptor antagonist activity and 5-HT₄ receptor agonist activity at the gastro-intestinal level.

5.2 Pharmacokinetic particulars

Metoclopramide is rapidly and completely absorbed after parenteral administration.

After subcutaneous administration to dogs and cats, maximum concentrations are obtained after 15 - 30 min.

Metoclopramide is rapidly distributed into most tissues and fluids, crosses the blood-brain barrier and enters the central nervous system.

Metoclopramide is metabolised by the liver.

The elimination of metoclopramide is rapid, 65 % of the dose being eliminated within 24 hours in the dog, primarily by the urinary route.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Store in the original package.

6.5 Nature and composition of immediate packaging

Vials of clear colourless glass type I, filled with 5, 10, 20, 25, 30 and 50 ml
Bromobutyl rubber stoppers type I (the stoppers are secured with aluminium caps)
1 vial in a cardboard box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
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8. MARKETING AUTHORISATION NUMBER

Vm 16849/4020

9. DATE OF FIRST AUTHORISATION

20 December 2010

10. DATE OF REVISION OF THE TEXT

December 2010