1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid 1 mg/ml oral solution for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Metoclopramide (as hydrochloride) ..... 0.891 mg
equivalent to metoclopramide hydrochloride ..... 1 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E 218)	1.3 mg
Propyl parahydroxybenzoate	0.2 mg
Hydroxyethylcellulose	
Sodium cyclamate	
Saccharin sodium	
Citric acid	
Flavouring: sweet orange	
Flavouring: apricot	
Purified water	

Clear to slightly opalescent liquid, viscous, colourless to slightly amber.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of gastro-intestinal perforation or obstruction.
Do not use in the case of gastro-intestinal haemorrhage.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species

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.
In case of vomiting after intake of the oral solution, maintain the usual interval between two administrations before administering the product again.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental ingestion, especially by children, 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.
Wash hands after administration to the animal.

Special precautions for the protection of the environment

Not applicable.

3.6 Adverse events

Dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Agitation[1], Aggression[1], Vocalisation[1] Ataxia[1], Abnormal movement [1], Tremor[1], Prostration[1]

[1]These observed extrapyramidal effects are transient and disappear when treatment is stopped.

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 authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laboratory studies in laboratory animals have not produced any evidence of 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.
Pregnancy and lactation:
Use only according to the benefit-risk assessment by the veterinarian.

3.8 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 3.6).
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.

3.9 Administration routes and dosage

Oral use. Administer the product directly into the mouth.

0.5 to 1 mg of metoclopramide hydrochloride per kg of body weight per day administered as either:

2.5 to 5.0 mg/10 kg (equivalent to 2.5 to 5 ml/10 kg), twice daily
or
1.7 to 3.3 mg/10 kg (equivalent to 1.7 to 3.3 ml/10 kg), three times daily.

Oral administrations can be repeated with interval of 6 hours.

3.10 Symptoms of overdose (and where applicable, emergency procedures, and antidotes)
Most of the clinical signs reported after an overdosage are well known extrapyramidal side effects (see section 3.6).
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.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code:

QA03FA01

4.2 Pharmacodynamics

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-HT_4 receptor agonist activity at the gastro-intestinal level.

4.3 Pharmacokinetics

Metoclopramide is rapidly and almost completely absorbed from the gastrointestinal tract following oral administration.
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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibilities studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening: 6 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Nature of container:
Coloured glass vial type III.
Child-proof stopper.

Pack size:
Cardboard box containing 1 vial of 125 ml.

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

Medicines should not be disposed of via wastewater or household waste.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/017/001

8. DATE OF FIRST AUTHORISATION

10 December 2010

9.DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

17 November 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)