ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 125 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid 1 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Metoclopramide 0.891 mg *i.e.* 1 mg metoclopramide hydrochloride

3. PACKAGE SIZE

125 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral solution

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}
Once opened, use within 6 months by ___/___/___

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 125 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid 1 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Metoclopramide 0.891 mg *i.e.* 1 mg metoclopramide hydrochloride

3. TARGET SPECIES

Dogs and cats

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months by ___/___/___

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

1. Name of the veterinary medicinal product

Emeprid 1 mg/ml oral solution for dogs and cats

2. Composition

Each ml contains:
Active substance:
Metoclopramide (as hydrochloride) 0.891 mg equivalent to 1 mg metoclopramide hydrochloride

Excipients:
Methyl parahydroxybenzoate (E218) 1.3 mg
Propyl parahydroxybenzoate 0.2 mg

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

3. Target species

Dogs and cats.

4. Indications for use

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

5. 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.

6. Special warnings

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.

Pregnancy and lactation:
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. The use of the product during pregnancy and lactation must be made according to the benefit/risk assessment carried out by the veterinarian.

Interactions:
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 Adverse events).
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.

Overdose:
Most of the clinical signs reported after an overdosage are well known extra pyramidal side effects (see section Adverse events).
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.

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

7. Adverse events

Dogs, cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Agitation[1], Aggression[1], Vocalisation[1], Ataxia (incoordination)[1], Abnormal movement[1], Tremor[1], Prostration (lying down)[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 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, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use. Administer the product directly into the mouth.

0.5 to 1 mg of metoclopramide hydrochloride per kg of body weight per day, divided in 2 or 3 administrations.

9. Advice on correct administration

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.

10. Withdrawal periods

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 6 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Pack sizes:
Cardboard box containing 1 vial of 125 ml

15. Date on which the package leaflet was last revised

{mm/yyyy}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, Z.I. Très le Bois, 22600 Loudéac, France

17. Other information

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.

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.