ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box 125 ml
Vial label 125 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid 1 mg/ml oral solution for dogs and cats
Metoclopramide hydrochloride [Not translated nationally on the immediate label]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Metoclopramide 0.891 mg *i.e.* 1 mg metoclopramide hydrochloride
Methyl parahydroxybenzoate (E 218) 1.3 mg
Propyl parahydroxybenzoate 0.2 mg

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

125 ml

5. TARGET SPECIES

Dogs, Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral solution
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: {month/year}
Once opened, use within 6 months by ___/___/___

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.
[Not required on the immediate label]

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.
[Not required on the immediate label]

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4053

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

Emeprid 1 mg/ml oral solution for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid 1 mg/ml oral solution for dogs and cats
Metoclopramide hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:
Metoclopramide (as hydrochloride) 0.891 mg equivalent to 1 mg metoclopramide hydrochloride
Methyl parahydroxybenzoate (E218) 1.3 mg
Propyl parahydroxybenzoate 0.2 mg

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

4. INDICATIONS

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 known 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. ADVERSE REACTIONS

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. These observed effects are transient and disappear when treatment is stopped.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Dogs, Cats

8. DOSAGE FOR EACH SPECIES, ROUTE 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 PERIOD

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 after the expiry date 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 WARNINGS

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.
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.

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.
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 reactions)..
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 reactions).
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

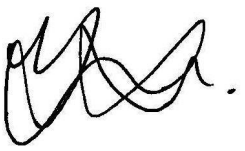
September 2022

15. OTHER INFORMATION

Pack sizes:
Cardboard box containing 1 vial of 125 ml

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

Pharmacokinetic particulars
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.



Approved: 13 September 2022