ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Metoclopramide 4.457 mg *i.e.* 5 mg metoclopramide hydrochloride

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous, intramuscular or subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {MM/YYYY}
Once opened, use within 28 days 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

Vm 15052/3014

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label: 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Metoclopramide hydrochloride: 5 mg/ml*[Not translated nationally on the immediate label]*
Metoclopramide 4.457 mg *i.e.*5 mg metoclopramide hydrochloride

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {MM/YYYY}
Once opened, use within 28 days by ___/___/___

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Emeprid 5 mg/ml solution for injection for dogs and cats

2. Composition

Each ml contains:
Active substance:
Metoclopramide (as hydrochloride) 4.457 mg equivalent to 5 mg metoclopramide hydrochloride

Excipient:
Metacresol 2 mg

Clear, colourless 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.

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.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
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. Use only according to the benefit/risk assessment by the veterinarian.

Interactions 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 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 compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Agitation[1], Aggression[1], Vocalisation[1], Ataxia (incoordination)[1], Abnormal movement[1], Tremor[1], Prostration (lying down)[1]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Allergic reaction

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

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] Allergic reaction

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

However, in very rare cases, more severe reactions were observed, that needed medical care.

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

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

9. Advice on correct administration

2.5 to 5.0 mg/10 kg (equivalent to 0.5 to 1 ml/10 kg), twice daily
or
1.7 to 3.3 mg/10 kg (equivalent to 0.34 to 0.6 ml/10 kg), three times daily.

Injections 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 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: 28 days.

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

Vm 5052/3014

Pack sizes:
Cardboard box containing 1 vial of 10 ml

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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, 10 av. de La Ballastière, 33500 Libourne, 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 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.

Approved: 11 May 2024