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 AND OTHER SUBSTANCES

1 ml contains:
Metoclopramide 4.457 mg i.e. 5 mg metoclopramide hydrochloride
Metacresol 2mg

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs, Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intravenous, intramuscular or subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days

Once opened, use by….

9. SPECIAL STORAGE PRECAUTIONS

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

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 15052/5047

15. BATCH NUMBER

Lot:

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emeprid.

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Metoclopramide hydrochloride: 5mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days

Once opened, use by….

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE 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 metoclopramide hydrochloride.....5 mg

Excipients:

Metacresol…….2mg

Clear, colourless solution

3. TARGET SPECIES

Dogs, 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 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. SPECIAL WARNING(S)

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.

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. The use of the product during pregnancy and lactation must be made according to the benefit/risk assessment carried out 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 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 (symptoms, emergency procedures, antidotes):
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 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[1], Abnormal movement NOS[1], Tremor[1], Prostration,[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[1], Abnormal movement NOS[1], Tremor[1], Prostration,[1] Allergic reaction

[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. National contact details : https://www.gov.uk/report-veterinary-medicine-problem

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD(S)

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 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V - To be supplied only on veterinary prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5047

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:

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
10 av. de La Ballastière
33500 Libourne
France

17. OTHER INFORMATION

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 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