ANNEX III

LABELLING AND PACKAGE LEAFLET

CLOQ day 196, clean version = final

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
5, 10, 20, 25, 30 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VOMEND 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Metoclopramide (as hydrochloride monohydrate)	4.457 mg
equivalent to metoclopramide hydrochloride	5 mg
Benzyl alcohol (E1519)	18 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5, 10, 20, 25, 30 and 50 ml

5. TARGET SPECIES

Dogs, cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Once opened, use by ___/___/___
Shelf-life after first opening: 28 days.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/5013

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
5 and 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VOMEND 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:

Metoclopramide (as hydrochloride monohydrate)	4.457 mg
equivalent to metoclopramide hydrochloride	5 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5, 10 ml

4. ROUTE(S) OF ADMINISTRATION

IM or SC use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}
Once opened, use by ___/___/___
Shelf-life after first opening: 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
20, 25, 30 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VOMEND 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Metoclopramide (as hydrochloride monohydrate)	4.457mg
equivalent to metoclopramide hydrochloride	5 mg
Benzyl alcohol (E1519)	18 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

20, 25, 30 and 50 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM or SC use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Once opened, use by ___/___/___
Shelf-life after first opening: 28 days.

11. SPECIAL STORAGE CONDITIONS

Store in the original package.

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

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/5013

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
for 5, 10, 20, 25, 30 and 50 ml

VOMEND 5 mg/ml solution for injection 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:
Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VOMEND 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Metoclopramide (as hydrochloride monohydrate)	4.457 mg
equivalent to metoclopramide hydrochloride	5 mg
Benzyl alcohol (E1519)	18 mg

Clear colourless aqueous 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 gastro-intestinal perforation or obstruction.

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. The observed effects are transient and disappear when treatment is stopped.
In very rare cases, allergic reactions may occur.
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

Intramuscular or subcutaneous use.
0.5 mg metoclopramide hydrochloride per kg BW, if necessary repeated every 6-8 hours.

9. ADVICE ON CORRECT ADMINISTRATION

5.0 mg/10 kg (equivalent to 1 ml/10 kg)
Injections can be repeated every 6-8 hours.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in the original package.
Do not use after the expiry date stated on the label and carton after EXP.
Shelf-life after first opening the immediate packaging: 28 days.

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.

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.

Use during pregnancy, lactation or lay
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
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
Do not mix with any other veterinary medicinal product.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{month/year}

15. OTHER INFORMATION

Pack sizes:
1 vial with 5, 10, 20, 25, 30 and 50 ml solution for injection.
1 vial in a cardboard box.

Not all pack sizes may be marketed.

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.