PART 1B-1

SUMMARY OF PRODUCT CHARACTERISTICS

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vomend 5 mg/ml solution for injection for dogs and cats
(Austria, Germany, Italy, Luxembourg, Portugal, The Netherlands, United Kingdom)

Vomend anti-emeticum 5 mg/ml solution for injection for dogs and cats
(Belgium, Spain)

Vomend Vet. 5 mg/ml solution for injection for dogs and cats
(Finland,)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

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

Excipient:

Benzyl alcohol (E1519)	18 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in cases of gastrointestinal perforation or obstruction.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 an adverse effect occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In some very rare cases(less than 1 animal in 10,000 animals, including isolated reports), 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.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in laboratory animals have not produced any evidence of teratogenic or foetotoxic effects. However, studies in 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.

4.8 Interaction 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 contraindication to the use of anticholinergic drugs.
Concurrent use of metoclopramide with neuroleptics derived from phenothiazine (acepromazine) and butyrophenones increases the risk of extrapyramidal effects (see section 4.6).
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.

4.9 Amounts to be administered and administration route

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Most of the clinical signs reported after an overdose are well known extrapyramidal side effects (see section 4.6).
In the absence of a specific antidote, it is recommended to offer a calm environment to the animal until the extrapyramidal side effects disappear.
Metoclopramide being rapidly metabolised and eliminated, side effects generally disappear quickly.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: propulsives.
ATCvet code: QA03FA01

5.1 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 gastrointestinal level.

5.2 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 minutes.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and composition of immediate packaging

Vials of clear colourless glass type I, filled with 5 ml, 10 ml, 20 ml, 25 ml, 30 ml and 50 ml.
Bromobutyl rubber stoppers type I (the stoppers are secured with aluminium caps).
1 vial in a cardboard box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: xxx xxxx
Date of last renewal: xxx xxxx

10. DATE OF REVISION OF THE TEXT

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vomend 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Austria, Germany, Italy, Luxembourg, Portugal, The Netherlands, United Kingdom)

Vomend anti-emeticum 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Belgium, Spain)

Vomend Vet. 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Finland)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs, cats

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous 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}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by: ___/___/___

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach 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)

xxxx

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial / Label: 20 ml, 25 ml, 30 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vomend 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Austria, Germany, Italy, Luxembourg, Portugal, The Netherlands, United Kingdom)

Vomend anti-emeticum 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Belgium, Spain)

Vomend Vet. 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Finland)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml, 25 ml, 30 ml and 50 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

--

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}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by: ___/___/___

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach 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)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial / Label: 5 ml and 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vomend 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Austria, Germany, Italy, Luxembourg, Portugal, United Kingdom, The Netherlands)

Vomend anti-emeticum 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Belgium, Spain)

Vomend Vet. 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Finland)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:
Active substance:

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 ml, 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}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by: ___/___/___

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

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 and manufacturer responsible for batch release:
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
(Austria, Germany, Italy, Luxembourg, Portugal, The Netherlands, United Kingdom)

Vomend anti-emeticum 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Belgium, Spain)

Vomend Vet. 5 mg/ml solution for injection for dogs and cats
Metoclopramide hydrochloride
(Finland)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains:

Active substance:

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

Excipient:

Benzyl alcohol (E1519)	18 mg

Clear, colourless, aqueous solution.

4. INDICATIONS

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

5. CONTRAINDICATIONS

Do not use in cases of gastrointestinal perforation or obstruction.

6. ADVERSE REACTIONS

In some very rare cases (less than 1 animal in 10,000 animals, including isolated reports), 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 package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intramuscular or subcutaneous use.
0.5 mg metoclopramide hydrochloride per kg body weight, 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 sight and reach of children.
Store in the original package.
Do not use this veterinary medicinal product after the expiry date which is 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 an adverse effect occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy or lactation:
Laboratory studies in laboratory animals have not produced any evidence of teratogenic or foetotoxic effects. However, studies in 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.

Interaction 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 contraindication to the use of anticholinergic drugs.
Concurrent use of metoclopramide with neuroleptics derived 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 overdose are well known extrapyramidal 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 the 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 veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{month/year}

15. OTHER INFORMATION

Pack sizes: 1 vial containing 5 ml, 10 ml, 20 ml, 25 ml, 30 ml or 50 ml solution for injection.
1 vial in a cardboard box.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.