ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mcepe 1 mg/ml oral solution for dogs and cats (AT, BE, CZ, DE, EL, ES, FR, HR, IT, NL, SK)
Mcepe, 1 mg/ml oral solution for dogs and cats (EE, LT, LV)
Emcepe vet 1 mg/ml oral solution for dogs and cats (SE, FI, DK, NO)
Emcepe 1 mg/ml oral solution for dogs and cats (PL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Metoclopramide (as hydrochloride monohydrate) 0.891 mg
equivalent to metoclopramide hydrochloride 1.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E 218)	1.30 mg
Propyl parahydroxybenzoate	0.20 mg
Hydroxyethylcellulose	
Sodium cyclamate	
Saccharin sodium	
Citric acid	
Flavouring: Honey	
Purified water	

Colourless to light brown, clear, viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
As metoclopramide is metabolised by the liver and primarily excreted by the urinary route, for animals with hepatic or renal insufficiency, due to an increase in the risk of side effects, a reduced dose should be used in accordance with the prescribing veterinarian.
Avoid administration to animals with diseases involving seizures (e.g. epilepsy or head trauma). 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:
This veterinary medicinal product may cause neurotoxic effects. Avoid accidental ingestion, especially by children. Do not leave the filled syringe unattended and store this veterinary medicinal product in a safe place. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
The active substance metoclopramide and the excipients methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause hypersensitivity reactions. People with known hypersensitivity to metoclopramide or the parabens should avoid contact with this veterinary medicinal product. If you develop symptoms following exposure, such as a skin rash, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

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

3.6 Adverse events

Dog, cat:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Agitation[1], aggression[1], vocalisation[1], Ataxia[1], abnormal movement[1], tremor[1], Prostration[1]

[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. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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 contra-indication 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 3.6).
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.

3.9 Administration routes and dosage

Oral use. Administer the veterinary medicinal product directly into the mouth.

0.5 to 1 mg of metoclopramide hydrochloride per kg body weight per day, administered as either:
0.25 to 0.5 mg/kg (equivalent to 0.25 to 0.5 ml/kg), twice daily
or
0.17 to 0.33 mg/kg (equivalent to 0.17 to 0.33 ml/kg), three times daily.

To ensure a correct dosage, body weight should be determined as accurately as possible.
For volumes below 0.3 mL, a 1 mL syringe will be needed.
Duration of treatment: in accordance with the prescribing veterinarian.
Oral administrations can be repeated at 6-hour intervals.

Application
Press and turn the cap. Insert the dosing oral syringe into the plastic adapter. Turn the bottle/syringe upside down and slowly pull the syringe plunger down until the line on the plunger matches the dose prescribed by your veterinarian. The oral syringe is graduated in ml.
By pressing the plunger, empty the contents of the syringe directly into the oral cavity. If necessary, the user can rinse the syringe with water and let it dry. Place the dry syringe in the box.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Most of the clinical signs reported after an overdosage are well known extrapyramidal side effects (see section 3.6).
In the absence of a specific antidote, it is recommended to offer a calm environment to the animal until extrapyramidal side effects disappear.
Metoclopramide is being rapidly metabolised and eliminated, side effects generally disappear quickly.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA03FA01

4.2 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Nature of container:
Brown glass vial type III with PP screw cap with child safety lock, LDPE-adapter and oral syringe (LDPE-body and PS-plunger).

Pack sizes:
Cardboard box containing 1 vial of 25 ml with a 3 ml oral syringe.
Cardboard box containing 1 vial of 100 ml with a 5 ml oral syringe.

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mcepe 1 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Metoclopramide (as hydrochloride monohydrate) 0.891 mg
equivalent to metoclopramide hydrochloride 1.0 mg

3. PACKAGE SIZE

25 ml with a 3 ml oral syringe
100 ml with a 5 ml oral syringe

4. TARGET SPECIES

Dogs, cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months – use 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

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mcepe 1 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Metoclopramide (as hydrochloride monohydrate) 0.891 mg
equivalent to metoclopramide hydrochloride 1.0 mg

3. TARGET SPECIES

Dogs, cats

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months – use by: __.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial 25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mcepe 1 mg/ml oral solution

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Metoclopramide (as hydrochloride monohydrate) 0.891 mg
equivalent to metoclopramide hydrochloride 1.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months – use by: __.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Mcepe 1 mg/ml oral solution for dogs and cats (AT, BE, CZ, DE, EL, ES, FR, HR, IT, NL, SK)
Mcepe, 1 mg/ml oral solution for dogs and cats (EE, LT, LV)
Emcepe vet 1 mg/ml oral solution for dogs and cats (SE, FI, DK, NO)
Emcepe 1 mg/ml oral solution for dogs and cats (PL)

2. Composition

Each ml contains:

Active substance:
Metoclopramide (as hydrochloride monohydrate) 0.891 mg
equivalent to metoclopramide hydrochloride 1.0 mg

Excipients:
Methyl parahydroxybenzoate (E 218) 1.30 mg
Propyl parahydroxybenzoate 0.20 mg

Colourless to light brown, clear, viscous 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 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:
As metoclopramide is metabolised by the liver and primarily excreted by the urinary route, for animals with hepatic or renal insufficiency, due to an increase in the risk of side effects, a reduced dose should be used in accordance with the prescribing veterinarian.
Avoid administration to animals with diseases involving seizures (e.g. epilepsy and head trauma). 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:
This veterinary medicinal product may cause neurotoxic effects. Avoid accidental ingestion, especially by children. Do not leave the filled syringe unattended and store this veterinary medicinal product in a safe place. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
The active substance metoclopramide and the excipients methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause hypersensitivity reactions. People with known hypersensitivity to metoclopramide or the parabens should avoid contact with this veterinary medicinal product. If you develop symptoms following exposure, such as a skin rash, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation:
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.
Use of the veterinary medicinal product during pregnancy and lactation should only be according to the benefit-risk assessment by the treating 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 contra-indication 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 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 extrapyramidal 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 is 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

Dog, cat:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Agitation[1], aggression[1], vocalisation[1], Ataxia[1], abnormal movement[1], tremor[1], Prostration[1]

[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 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: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use. The veterinary medicinal product should be administered directly into the mouth.

0.5 to 1 mg metoclopramide hydrochloride per kg body weight per day, administered as either:
0.25 to 0.5 mg/kg (equivalent to 0.25 to 0.5 ml/kg), twice daily
or
0.17 to 0.33 mg/kg (equivalent to 0.17 to 0.33 ml/kg), three times daily.

To ensure a correct dosage, body weight should be determined as accurately as possible.
For volumes below 0.3 mL, a 1 mL syringe will be needed.
Duration of treatment: in accordance with the prescribing veterinarian.
Oral administrations can be repeated at 6-hour intervals.

9. Advice on correct administration

See section: “Dosage for each species, routes and method of administration”

Application
Press and turn the cap. Insert the dosing oral syringe into the plastic adapter. Turn the bottle/syringe upside down and slowly pull the syringe plunger down until the line on the plunger matches the dose prescribed by your veterinarian. The oral syringe is graduated in ml.
By pressing the plunger, empty the contents of the syringe directly into the oral cavity. If necessary, the user can rinse the syringe with water and let it dry. Place the dry syringe in the box.

10. Withdrawal periods

Not applicable.

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 is 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 immediate packaging: 6 months.

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 authorisation numbers and pack sizes

Cardboard box containing 1 vial of 25 ml with a 3 ml oral syringe.
Cardboard box containing 1 vial of 100 ml with a 5 ml oral syringe.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Tel: +49-(0)5136-6066-0

17. Other information