ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl 2.5 mg/ml solution for injection
metoclopramide hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Metoclopramide (as hydrochloride monohydrate) 2.23 mg
equivalent to metoclopramide hydrochloride 2.5 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 ml
10 ml
20 ml
25 ml
30 ml
50 ml

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
SC, IM

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days. Use by…

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.
Do not freeze.

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

Disposal: read package leaflet.

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4007

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5, 10, 20, 25, 30 or 50 ml flasks

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl 2.5 mg/ml injection for cats and dogs
metoclopramide hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Metoclopramide hydrochloride: 2.5 mg/ml

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

5 ml
10 ml
20 ml
25 ml
30 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

SC, IM

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by: …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Metomotyl 2.5 mg/ml solution for injection for cats and dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl 2.5 mg/ml solution for injection for cats and dogs
metoclopramide hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Metoclopramide (as hydrochloride monohydrate)	2.23 mg
equivalent to metoclopramide hydrochloride	2.5 mg

Excipients:

Metacresol	2 mg

Clear colourless solution.

4. INDICATION(S)

Symptomatic treatment of vomiting and reduced gastro-intestinal movement associated with an inflamed stomach (gastritis), spasm of the pylorus, chronic inflammation of the kidneys (nephritis) and digestive intolerance to some drugs. Prevention of vomiting after surgery.

5. CONTRAINDICATIONS

Do not use in cases of gastrointestinal perforation or obstruction.
Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with gastrointestinal bleeding.

6. ADVERSE REACTIONS

Drowsiness and diarrhoea could be observed after treatment.
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 package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats and dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular or subcutaneous use

0.5 to 1 mg of metoclopramide hydrochloride per kg of body weight per day by intramuscular or subcutaneous routes, divided in 2 or 3 administrations:
- for twice daily administration: 2.5 to 5 mg/10 kg of body weight per injection i.e. 1 to 2 ml/10 kg of body weight per injection.
- for administration 3 times a day: 1.7 to 3.3 mg/10 kg of body weight per injection i.e. 0.68 to 1.32 ml/10 kg of body weight per injection.

The interval between two administrations should be at least 6 hours.

The stopper should not be punctured more than 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Do not freeze.
Shelf-life after first opening of the immediate packaging: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals

The dosage must be adapted in animals with kidney failure or liver failure(due to an increase in the risk of side effects).
Avoid administration to animals with seizure disorders or head trauma. Avoid in dogs with false pregnancy.

Avoid administration to animals with epilepsy. The dosage should be carefully observed, especially in cats and small breed dogs.
In animals with a certain tumor of the adrenal glands (pheochromocytoma), metoclopramide may induce a dangerously high blood pressure (hypertensive crisis).
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 spillage onto 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.

Interaction with other medicinal products and other forms of interaction

In cases of inflamed stomach (gastritis), avoid the co-administration of anticholinergic drugs (such as atropine) as they may counteract the effects of metoclopramide on gastrointestinal movement.
In cases of simultaneous diarrhoea, there is no contraindication to the use of anticholinergic drugs.
Concurrent use of metoclopramide with medicines to treat mentall illness (neuroleptics) derivated from the substance phenothiazine (acepromazine) and substances called butyrophenones increases the risk of so-called extrapyramidal effects (see section 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.

Incompatibilities

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

Pregnancy, lactation

Laboratory studies in laboratory animals have not produced any evidence of abnormal development or danger to the foetus. 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.

Overdose (symptoms, emergency procedures, antidotes)

Most of the clinical signs reported after an overdosage are well-known “extrapyramidal” side effects (see section 6).
In the absence of a specific antidote, it is recommended to offer a calm environment to the animal until side effects disappear.
Metoclopramide being rapidly metabolised and eliminated, side effects generally disappear quickly.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD month YYYY

15. OTHER INFORMATION

Pack sizes:
Cardboard box containing 1 vial of 5, 10, 20, 25, 30 or 50 mL.

Not all pack sizes may be marketed.