[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl 10 mg chewable tablets for dogs (AT, DE, HR, NL, NO, SI)
Metomotyl 10 chewable tablets for dogs (FR)
Vomend vet 10 mg chewable tablets for dogs (BE, DK, FI, SE, PL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Metoclopramide (as hydrochloride monohydrate) 8.92 mg
(equivalent to 10.0 mg metoclopramide hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents
Yeast (dried)
Chicken flavour
Lactose, anhydrous
Croscarmellose sodium
Magnesium stearate

Light brown with brown spots, round and convex 7 mm tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Alleviation of symptoms such as frequent vomiting, gastric dilatation, chronic gastritis, duodenal-gastric reflux and diarrhoea associated with reduced gastro-intestinal motility.

3.3 Contraindications

Do not use in cases of gastrointestinal haemorrhage, perforation or obstruction.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Do not use in dogs weighing less than 10 kg.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid administration to animals with seizure disorders, e.g. epilepsy, or head trauma.

As metoclopramide may elevate the prolactin levels, care should be taken when use in dogs with pseudopregnancy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause neurological effects after accidental ingestion, particularly by children.
Children should not come into contact with the veterinary medicinal product. Unused tablet parts should be returned into the open blister and carton and carefully kept away from children and always be used at the next administration.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Drowsiness Diarrhoea Neurological effects [a] (agitation, ataxia, abnormal positions and/or movements, prostration, tremors and aggression, vocalisation)

[a] The observed effects are transient and disappear after discontinuation of the treatment.

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 its local representative 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:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible 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 contraindication to the use of anticholinergic drugs.
Concurrent use of metoclopramide with neuroleptics derived from phenothiazine (acepromazine) and butyrophenones increases the risk of neurological 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

For oral use.
The recommended dose is 0.22 mg metoclopramide (equivalent to 0.25 mg metoclopramide hydrochloride) per kg bodyweight, 4 times a day.

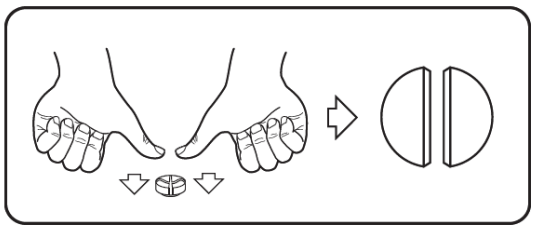
The following table is intended as a guide to dispensing the veterinary medicinal product:

Body weight kg	Dose mg/animal*	Metomotyl 5 mg		Metomotyl 10 mg
5-7.5	1.25			
>7.5-12.5	2.5		OR	
>12.5-17.5	3.75			
>17.5 -22.5	5		OR	
>22.5-27.5	6.25			
>27.5-32.5	7.5		OR	
>32.5-37.5	8.75			
>37.5-45	10		OR	
>45-55	12.5		OR	
>55-65	15		OR	
>65-75	17.5		OR	
>75-85	20		OR	

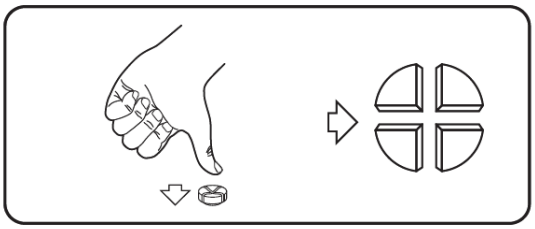
= ¼ Tablet = ½ Tablet = ¾ Tablet = 1 Tablet

* dose in mg metoclopramide hydrochloride per animal per dosing.

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



2 equal parts: press down with your thumbs on both sides of the tablet.



4 equal parts: press down with your thumb in the middle of the tablet.

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

In case of overdose no other adverse reactions are known than those mentioned in section 3.6.

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

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 gastroduodenal 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-HT4 receptor agonist activity at the gastrointestinal level.

4.3 Pharmacokinetics

Metoclopramide is rapidly and completely absorbed after oral administration.
Metoclopramide is rapidly distributed into most tissues and fluids, crosses the blood-brain barrier.
Metoclopramide is metabolised by the liver. The elimination of metoclopramide is primarily by the urinary route.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:3 years.
Shelf life of divided tablets: 3 days.

5.3 Special precautions for storage

Any unused tablet parts should be returned to the open blister and carton.

5.4 Nature and composition of immediate packaging

OPA/ALU/PVC//ALU blisters containing 10 tablets.
Cardboard box containing 10 or 100 tablets.

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

{name}

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

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

{DD/MM/YYYY}

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

Metomotyl 10 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:
Metoclopramide (as hydrochloride monohydrate) 8.92 mg
(equivalent to 10.0 mg metoclopramide hydrochloride)

3. PACKAGE SIZE

10 tablets
100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of divided tablets: 3 days.

9. SPECIAL STORAGE PRECAUTIONS

Any unused tablet parts should be returned to the open blister and carton.

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

{name}

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Metoclopramide hydrochloride 10 mg per tablet.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Metomotyl 10 mg chewable tablets for dogs (AT, DE, HR, NL, NO, SI)
Metomotyl 10 chewable tablets for dogs (FR)
Vomend vet 10 mg chewable tablets for dogs (DK, BE, FI, SE, PL)

2. Composition

Each tablet contains:

Active substance:
Metoclopramide (as hydrochloride monohydrate) 8.92 mg
(equivalent to 10.0 mg metoclopramide hydrochloride)

Light brown with brown spots, flavoured, round and convex 7 mm tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

3. Target species

Dogs.

4. Indications for use

Alleviation of symptoms such as frequent vomiting, gastric dilatation, chronic gastritis, duodenal-gastric reflux and diarrhoea associated with reduced gastro-intestinal motility.

5. Contraindications

Do not use in cases of gastrointestinal haemorrhage, perforation or obstruction.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Do not use in dogs weighing less than 10 kg.

Special precautions for safe use in the target species:
Avoid administration to animals with seizure disorders, e.g. epilepsy, or head trauma.
As metoclopramide may elevate the prolactin levels, care should be taken when use in dogs with pseudopregnancy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause neurological effects after accidental ingestion, particularly by children.
Children should not come into contact with the veterinary medicinal product. Unused tablet parts should be returned into the open blister and carton and carefully kept away from children and always be used at the next administration.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible 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 neurological 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:
In case of overdose no other adverse reactions are known than those mentioned in section "Adverse events".

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Drowsiness Diarrhoea Neurological effects [a] (agitation, ataxia, abnormal positions and/or movements, prostration, tremors and aggression, vocalisation)

[a] The observed effects are transient and disappear after discontinuation of the treatment.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

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

For oral use.
The recommended dose is 0.22 mg metoclopramide (equivalent to 0.25 mg metoclopramide hydrochloride) per kg bodyweight, 4 times a day.

The following table is intended as a guide to dispensing the veterinary medicinal product:

Body weight kg	**Dose mg/animal***	**Metomotyl 5 mg**		**Metomotyl 10 mg**
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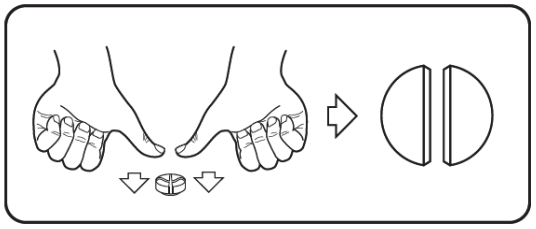
>65-75	17.5		OR	
>75-85	20		OR	

 = ¼ Tablet  = ½ Tablet  = ¾ Tablet  = 1 Tablet

* dose in mg metoclopramide hydrochloride per animal per dosing.

9. Advice on correct administration

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



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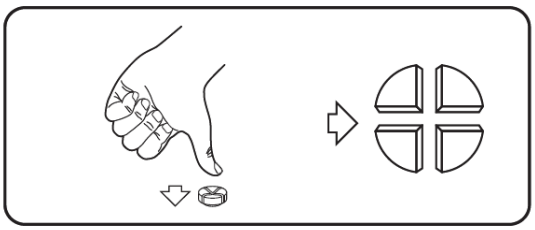

4 equal parts: press down with your thumb in the middle of the tablet.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf life of divided tablets: 3 days.
Any unused tablet parts should be returned to the open blister and carton.

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 or pharmacist 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

MA number:

Cardboard box of 1 or 10 blister(s).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/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:
{name}

Manufacturer responsible for batch release:
Lelypharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

Or

Genera d.d.
Svetonedeljska cesta 2, Kalinovica
HR-10436 Rakov Potok
Croatia

Local representatives and contact details to report suspected adverse reactions:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information