1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Metoclopramide 2.23 mg
equivalent to metoclopramide hydrochloride 2.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Metacresol	2 mg
Sodium chloride	
Water for injections	

Clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats and dogs.

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. Prevention of vomiting after surgery.

3.3 Contraindications

Do not use in cases of :
- gastro-intestinal perforation or obstruction.
- gastro-intestinal haemorrhage.
- hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 seizure disorders or head trauma. Avoid in dogs with pseudopregnancy.

Avoid administration to animals with epilepsy. The dosage should be carefully observed, especially in cats and small breed dogs.
In animals with pheochromocytoma, metoclopramide may induce a 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.

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):	Extrapyramidal effects (agitation, ataxia, abnormal positions and/or movements, prostration, tremors and aggression, vocalisation)* Allergic reaction

*The observed effects are transient and disappear when treatment is stopped.

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Extrapyramidal effects (agitation, ataxia, abnormal positions and/or movements, prostration, tremors and aggression, vocalisation)* Allergic reaction Drowsiness Diarrhoea

*The observed 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 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:
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 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 gastro-intestinal 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 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

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.

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 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 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 gastro-intestinal level.

4.3 Pharmacokinetics

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.

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: 28 days

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Nature of container:
Clear colourless type I glass vial
Red chlorobutyl 20 mm stopper
Aluminium 20 mm cap

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

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

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/009/001

8. DATE OF FIRST AUTHORISATION

12 September 2014

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

24 November 2023

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).