

Item Code	: Draft 24 Apr 25
PM Code	: Ins.P. - PII (AU)
Measurement(mm) ± 2mm	: 260(L) x 220(W)
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Cursor (Attachment 2)	:
Colour of Artwork	: <b>K</b>
Source of Artwork	: MAC 2 / CC

# VGrade Metoclopramide Injection 5mg/ml

## 1. NAME OF THE VETERINARY MEDICINE

VGrade Metoclopramide Injection 5mg/ml

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One mL contains:

### Active substance:

Metoclopramide Hydrochloride ..... 5mg  
(Equivalent to 5 mg of metoclopramide hydrochloride)

### Product Description:

A clear and colourless solution

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs and cats.

### 3.2 Indications for use for each target species

Symptomatic treatment of vomiting and reduced gastrointestinal motility, particularly in gastritis, pyloric spasm, chronic nephritis and digestive intolerance to certain medications.

### 3.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use for gastrointestinal perforation or obstruction.

Do not use in case of gastrointestinal bleeding.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

#### Special precautions for safe use in target species

Adjust the dosage in patients with renal or hepatic insufficiency (increased risk of adverse effects). Avoid administration to epileptic animals. Respect the prescribed doses, particularly in small dogs and cats.

Following prolonged vomiting, treatment, such as fluid therapy and electrolyte rebalancing, may be carried out.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash your hands after administering the product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the doctor.

In case of accidental contact with the eyes or skin, rinse immediately and thoroughly with water. If any adverse reactions occur, seek medical advice immediately and show the package leaflet or label to the doctor.

#### Special precautions for environmental protection

Not applicable.

#### Other precautions

## 3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Agitation <sup>1</sup> , Aggression <sup>1</sup> , Vocalization <sup>1</sup> , Ataxia <sup>1</sup> , Abnormal movements <sup>1</sup> , tremors <sup>1</sup> , Prostration <sup>1</sup>
Very rare (< 1 animal / 10,000 animals treated, including isolated cases):	Allergic reaction

<sup>1</sup>These extrapyramidal effects are generally transient and disappear when treatment is stopped.

Cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated cases):	Agitation <sup>1</sup> , Aggression <sup>1</sup> , Vocalization <sup>1</sup> , Ataxia <sup>1</sup> , Abnormal movements <sup>1</sup> , Tremors <sup>1</sup> , Prostration <sup>1</sup> , Allergic reaction
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<sup>1</sup>These extrapyramidal effects are generally transient and disappear when treatment is stopped.

However, in very rare cases, more severe reactions have been observed, requiring medical attention.

## 3.7 Use during pregnancy, lactation or laying

Studies in laboratory animals have not shown teratogenic or fetotoxic effects.

However, studies in laboratory animals are limited and the safety of the active substance has not been studied in the target species.

### Gestation and lactation:

Use should only be made after an assessment of the benefit/risk ratio established by the responsible veterinarian.

## 3.8 Drug interactions and other forms of interaction

Avoid the administration of anticholinergics (atropine) in gastritis, as they can neutralize the effects of metoclopramide on gastrointestinal motility.

In concomitant diarrhea, there are no contraindications to the use of anticholinergics.

The combination of metoclopramide with phenothiazine-derived neuroleptics (acepromazine) increases the risk of extrapyramidal effects (see section "Undesirable effects").

Metoclopramide can potentiate the action of central nervous system depressants. In case of combination, it is advisable to use the low dose of metoclopramide to avoid excessive sedation.

## 3.9 Routes of administration and dosage

Intravenous, intramuscular or subcutaneous route.

0.45 to 0.89 mg of metoclopramide per kg of body weight per day, equivalent to 0.5 to 1 mg of metoclopramide hydrochloride per kg of body weight per day, to be administered as follows:  
either 2.5 to 5.0 mg of metoclopramide hydrochloride per 10 kg (equivalent to 0.5 to 1 mL/10 kg), 2 times a day  
or 1.7 to 3.3 mg of metoclopramide hydrochloride per 10 kg (equivalent to 0.34 to 0.66 mL/10 kg), 3 times a day.

The interval between two administrations should not be less than 6 hours.

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

Most of the clinical signs observed after an overdose are the well-known extrapyramidal effects (see section "Undesirable effects").

In the absence of a specific antidote, it is recommended to provide a quiet environment for the animal until the extrapyramidal effects disappear.

As metoclopramide is rapidly metabolized and eliminated, these adverse effects disappear rapidly.

### 3.11. Specific restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to reduce the risk of development of resistance

Not applicable.

### 3.12 Waiting time

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet Code

QA03FA01.

### 4.2 Pharmacodynamic properties

Metoclopramide is an original molecule of the orthopramide series.

The antiemetic action of metoclopramide is mainly due to its antagonist activity of D2 receptors in the central nervous system preventing nausea and vomiting caused by most stimuli. The prokinetic effect on gastroduodenal transit (increases the intensity and rhythm of stomach contractions and causes the opening of the pylorus) is due to its 5-HT<sub>4</sub> receptor agonist activity, its D2 receptor antagonist activity and its muscarinic activity, at the gastrointestinal level.

### 4.3 Pharmacokinetic properties

Following parenteral administration, metoclopramide is rapidly and completely absorbed.

After subcutaneous administration in dogs and cats, C<sub>max</sub> (maximum plasma concentrations) are reached within 15 to 30 minutes.

Metoclopramide is rapidly distributed to most tissues and fluids and crosses the blood-brain barrier into the central nervous system.

Metoclopramide is metabolized by the liver. Its elimination is rapid and occurs primarily in the urine.

### Environmental properties

## 5. PHARMACEUTICAL DATA

### 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

3 years.

### 5.3 Special precautions for storage

Store at temperature below 30°C. Protect from light and moisture.

### 5.4 Nature and composition of immediate packaging

Nature of container: Amber glass ampoule.

Pack size: 2ml x 10 amber ampoules.

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

Do not dispose of medicines down the drain or in household waste.

Use the take-back arrangements in place for the disposal of any unused veterinary medicinal product or waste derived from it, in accordance with local requirements and any national collection system applicable to the veterinary medicinal product concerned.

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(±2mm)



Manufacturer and Product Registration Holder:  
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