SUMMARY OF PRODUCT CHARACTERISTICS

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

Excipients:
Metacresol 2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection. Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats and dogs

4.2 Indications for use, specifying the 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.

4.3 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 hemorrhage.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 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. The use of the product during pregnancy and lactation must be made according to the benefit/risk assessment carried out by the veterinarian.

4.8 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 derivated from phenothiazine (acepromazine) and butyrophenones increases the risk of extrapyramidal effects (see section 4.6).
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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Most of the clinical signs reported after an overdosage are well-known extrapyramidal side effects (see section 4.6).
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.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: drugs for functional gastrointestinal disorders, propulsives
ATCvet code: QA03FA01

5.1 Pharmacodynamic properties

Metoclopramide is an original orthopramide molecule.
The anti-emetic action of metoclopramide is mainly due to its antagonist activity at D_2 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, D_2 receptor antagonist activity and 5-HT_4 receptor agonist activity at the gastrointestinal level.

5.2 Pharmacokinetic particulars

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 hr in the dog, primarily by the urinary route.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Metacresol
Sodium chloride
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening of the immediate packaging: 28 days

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 41821/4007

9. DATE OF FIRST AUTHORISATION

9 September 2014

10. DATE OF REVISION OF THE TEXT

December 2017

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

Approved: 20 December 2017