PARTICULARS TO APPEAR ON THE OUTER PACKAGE { OUTER CARTON }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:

Metoclopramide	4.457 mg
equivalent to metoclopramide hydrochloride	5 mg

Metacresol
Sodium chloride
Water for injections

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats and dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use
Intramuscular use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}Once broached use within 28 days. Use by…

9. SPECIAL STORAGE PRECAUTIONS

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

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

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/5014

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {FLASKS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

metoclopramide hydrochloride 5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}Once broached, use by: …

5. ROUTE(S) OF ADMINISTRATION

SC, IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metomotyl 5 mg/ml solution for injection for cats and dogs

2. COMPOSITION

Each ml contains:

Active substance:

Metoclopramide	4.457 mg
equivalent to metoclopramide hydrochloride	5 mg

Excipients:

Metacresol	2 mg

Clear colourless solution.

3. TARGET SPECIES

Cats and dogs

4. INDICATIONS FOR USE

Symptomatic treatment of vomiting and reduced gastro-intestinal motility associated with inflamed stomach (gastritis), spasms 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:
- gastro-intestinal perforation or obstruction.
- gastro-intestinal bleeding.
- hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNING(S)

Special precautions for safe use in the target species:
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.

Pregnancy and 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. Use according to the benefit/risk assessment by the responsible veterinarian.

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 gastro-intestinal movement.
In cases of simultaneous diarrhoea, there is no contraindication to the use of anticholinergic drugs.
Concurrent use of metoclopramide with medicines to treat mental illness (neuroleptics) derived from the substance phenothiazine (acepromazine) and substances called butyrophenones increases the risk of so-called extrapyramidal effects (see section 7).
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:
Most of the clinical signs reported after an overdosage are well-known extrapyramidal side effects (see section Adverse events).
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.

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

7. ADVERSE EVENTS

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Extrapyramidal effects (agitation, ataxia (incoordination), 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 (incoordination), 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 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:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk.

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. 0.5 to 1 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. 0.34 to 0.66 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

The stopper should not be punctured more than 20 times.

10. WITHDRAWAL PERIOD(S)

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 after Exp. 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 PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
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

Vm 41821/5014

Pack sizes:
Cardboard box containing 1 vial of 5, 10, 20, 25, 30 or 50 mL.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

December 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

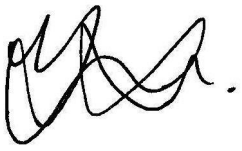
Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

POM-V



Approved: 13 March 2024