PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON MARBOCYL SA 200MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl SA 200mg POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Lyophilisate vial
Marbofloxacin 200mg
Disodium edetate 20mg
Benzalkonium chloride 2mg
Excipient to 1000mg
Solvent vial
Water for injections 20mL
Reconstituted solution:
Marbofloxacin 10.00mg
Disodium edetate 1.00mg
Benzalkonium chloride 0.10mg
Excipient to 1mL

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. PACKAGE SIZE

2 vials of 20ml.

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

In **dogs**, MARBOCYL SA for injection is indicated:
- in the treatment of infected wounds and subcutaneous abcesses due to Staphylococcus intermedius, Staphylococcus aureus, Escherichia coli, Pasteurella spp. and Pseudomonas spp.
- in the treatment of lower urinary tract infections due to Escherichia coli and Proteus spp.

In **cats**, MARBOCYL SA for injection is indicated:
- in the treatment of infected wounds and subcutaneous abcesses due to Pasteurella multocida, Staphylococcus intermedius, Staphylococcus aureus,

Staphylococcus
spp., Enterobacter spp. and Klebsiella spp. Marbofloxacin is inactive against anaerobic bacteria.

7. CONTRA-INDICATIONS

Marbofloxacin should not be used in dogs aged less than 12 months or less than 18 months for exceptionally large breed of dogs, such as Great Danes or mastiffs with a longer growth period.

Do not use in cases of resistance to other fluoroquinolones (cross-resistance).

Do not use in cases of hypersensitivity to the active substance, to any other quinolones or to any of the excipients.

8. METHOD AND ROUTE(S) OF ADMINISTRATION

For reconstitution details, see package leaflet.
DOGS: Treatment of infected wounds and s.c.abscesses: 2mg/kg (1mL/5kg) in a single s.c. or i.v. injection, followed the next day by administration of Marbocyl tablets at 2mg/kg for 6 days.
Treatment of lower urinary tract infections: 2mg/kg (1mL/5kg) in a single s.c. or i.v. injection, followed the next day by administration of Marbocyl tablets at 2mg/kg for at least 10 days and up to 28 days.
CATS: Treatment of infected wounds and s.c. abscesses: 2mg/kg/day by s.c. or i.v. injection for 3 to 5 days.

9. WITHDRAWAL PERIOD

Not applicable

10. SPECIAL WARNING(S), IF NECESSARY

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE PRODUCT TO ANIMALS: People with known hypersensitivity to (fluoro)quinolones should avoid using this product.
In case of contact with skin or eyes, rinse with plenty of water.
Accidental self-injection can induce a slight irritation.
In case of accidental self-injection, seek medical advice and show the label to the doctor.
Wash hands after use.

DO NOT OVERDOSE

SPECIAL PRECAUTIONS FOR USE – DURING PREGNANCY AND LACTATION:
See leaflet

11. EXPIRY DATE

Once reconstituted, use by:

12. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.
The reconstituted solution should be stored below 25°C and protected from light.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.
Keep the container in the outer carton.
Any reconstituted product remaining after 28 days should be discarded.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution*

For animal treatment only.
To be supplied only on Veterinary prescription.

POM-V

15. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

16. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

17. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4079

18. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – POWDER
LABEL MARBOCYL SA 200MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl SA 200mg POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Lyophilisate vial
Marbofloxacin 200mg
Disodium edetate 20mg
Benzalkonium chloride 2mg
Excipient to 1000mg

3. PHARMACEUTICAL FORM

Powder for solution for injection.

4. PACKAGE SIZE

200mg vial.

5. TARGET SPECIES

Dogs and cats.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

For subcutaneous and intravenous administration. For instructions for reconstitution see package leaflet.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

Do not overdose.

10. EXPIRY DATE

Exp:
Once reconstituted use by:

11. SPECIAL STORAGE CONDITIONS

The product and reconstituted solution should not be stored above 25°C and should be protected from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any reconstituted product remaining 28 days after preparation should be discarded.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4079

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – SOLVENT LABEL MARBOCYL SA 200MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for use with Marbocyl SA 200mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Water for injections

3. PHARMACEUTICAL FORM

Solvent for use with Marbocyl SA 200 mg Water for injections

4. PACKAGE SIZE

20ml vial.

5. TARGET SPECIES

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Use only as a solvent for Marbocyl SA 200 mg powder (For subcutaneous and intravenous administration).

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Steadings Barn
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Nr. Alderton
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NN12 7LS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4079

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL SA 200MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyophilisate vial Active ingredient
Marbofloxacin 200mg
Preservatives
Disodium edetate 20mg
Benzalkonium chloride 2mg
Excipient to. 1000mg

Solvent vial
Water for injections 20mL

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

In dogs, Marbocyl SA is indicated:
- in the treatment of infected wounds and subcutaneous abcesses due to Staphylococcus intermedius, Staphylococcus aureus, Escherichia coli, Pasteurella spp. and Pseudomonas spp.
- in the treatment of lower urinary tract infections due to Escherichia coli and Proteus spp.

In cats, Marbocyl SA for injection is indicated:
- in the treatment of infected wounds and subcutaneous abcesses due to Pasteurella multocida, Staphylococcus intermedius, Staphylococcus aureus, Staphylococcus spp., Enterobacter spp. and Klebsiella spp.

Marbofloxacin is inactive against anaerobic bacteria.

4.3 Contra-indications

Marbofloxacin should not be used in dogs aged less than 12 months or less than 18 months for exceptionally large breeds of dogs, such as Great Danes or mastiffs with a longer growth period.

Do not use in cases of resistance to other fluoroquinolones (cross-resistance).
Do not use in cases of hypersensitivity to the active substance, to any other quinolones or to any of the excipients.

4.4 Special warnings for each target species

4.5 Special precautions for use

(i) Special precautions for use in animals

Fluoroquinolones have been shown to induce erosion of articular cartilage in juvenile dogs and care should be taken to dose accurately especially in young animals.

Fluoroquinolones are also known for their potential neurological side effects. Cautious use is recommended in dogs and cats diagnosed as suffering from epilepsy.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly or are expected to respond poorly to other classes of antimicrobials. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may reduce effectiveness of treatment with other quinolones due to the potential for cross-resistance.

Official and local antimicrobial policies should be taken into account when the product is used.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to (fluro)quinolones should avoid using this product.
In case of contact with skin or eyes, rinse with plenty of water.
Accidental self-injection can induce a slight irritation.
In case of accidental self-injection, seek medical advice and show the label to the doctor.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

After subcutaneous administration, no undesirable effect is observed up to 2 times the recommended therapeutic dose in dogs or 3 times the recommended dose in cats.
After I.V. administration at 4mg/kg, rare mild and transitory side effects have been reported:

- Ptyalism (excess salivation)

- Nervous disorders : vocalization, excitation, and trembling (myoclonia)

- Very rarely, hypersensitivity reactions, diarrhoea and vomiting have been reported

The frequency of adverse reactions is defined using the following convention:
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Studies carried out with laboratory animals showed no embryotoxic, foetotoxic or teratogenic effects. However, no specific studies have been carried out on pregnant cats or dogs.

4.8 Interaction with other medicinal products and other forms of interaction

The dosage of theophylline must be reduced when used concurrently.

4.9 Amounts to be administered and administration route

Reconstitution:
- Before use, reconstitute the lyophilized powder using the solvent (water for injections) provided for the 200mg vial. Using aseptic technique withdraw 20mL from the vial of solvent and add rapidly to the lyophilised powder. When reconstituted in this way, the solution contains 10mg marbofloxacin per mL.

In **dogs**, the recommended doses and durations of treatment are: For the treatment of infected wounds and subcutaneous abscesses
- a single subcutaneous or intravenous injection, at a dosage of 2mg/kg (1mL/5kg), followed the next day by administration of Marbocyl Tablets daily at a dosage of 2mg/kg for 6 days.

For the treatment of lower urinary tract infections
a single subcutaneous or intravenous injection, at a dosage of 2mg/k (1mL/5kg), followed the next day by administration of Marbocyl Tablets daily at 2mg/kg for at least 10 days and up to 28 days.

In **cats**, the recommended doses and durations of treatment are: For the treatment of infected wounds and subcutaneous abscesses
- 2 mg/kg/day (0.2mL/kg/day), by subcutaneous or intravenous injection followed by subcutaneous injections for a total of 3 to 5 days.

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

Overdosage may cause acute signs in the form of neurological disorders, hypersalivation or trembling which should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

ATC vet code: QJ01MA93

5.1 Pharmacodynamic properties

Marbofloxacin is a synthetic bactericidal anti-infective, belonging to the fluoroquinolone group. It acts by inhibition of DNA gyrase. It is effective against a wide range of Gram positive bacteria (in particular Staphylococcus spp), Gram negative (Escherichia coli, Salmonella typhimurium, Campylobacter jejunii, Citrobacter freundii, Enterobacter cloacae, Serratia marcescens, Morganella morganii, Proteus spp, Klebsiella spp, Shigella spp, Bordetella bronchiseptica, Mannheimia haemolytica, Pasteurella multocida, Pseudomonas spp, Brucella canis) as well as Mycoplasma.

5.2 Pharmacokinetic properties

After subcutaneous administration at the recommended dose of 2mg/kg to dogs and cats, marbofloxacin is rapidly absorbed and its bioavailability is close to 100%. After subcutaneous administration of 2mg/kg in dogs and cats, the maximum plasma concentration achieved is 1.5µg/mL.
IV administration results in a similar pharmacokinetic profile for Area Under the Time Curve (AUC) and elimination (T1/2) values. Marbofloxacin is weakly bound to plasma proteins (< to 10% in dogs and cats) and is extensively distributed. In most tissues (skin, muscles, liver, kidney, lungs, bladder, digestive tract), tissue concentrations are higher than in plasma.
Marbofloxacin is slowly eliminated (Elimination half life from 10 to14h in both species), mainly in active form in urine (2/3), and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

6.2 Shelf life

Any reconstituted product remaining 28 days after preparation should be discarded.

6.4 Special precautions for storage

The reconstituted solution should not be stored above 25°C and should be protected from light.
Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

MARBOCYL SA, is packaged in amber glass Type II vials containing 200mg marbofloxacin in the form of a white freeze dried powder, colourless
Type II glass vials of solvent are supplied which contain 20mL Water for Injections Ph.Eur..

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials

Unused product and containers should be disposed of in accordance with any guidance from an appropriate waste regulation authority.
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

The discard date should be calculated at the time of reconstitution and written in the space provided on the carton. Any reconstituted product remaining in the vial should be discarded after 28 days.

7. MARKETING AUTHORISATION HOLDER

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Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4079

9. DATE OF FIRST AUTHORISATION

October 2023

10. DATE OF REVISION OF THE TEXT FINAL INFORMATION

Marbocyl is a trademark of Vetoquinol SA Keep out of the reach of children.
To be supplied only on veterinary prescription
For animal treatment only

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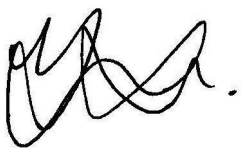

Approved: 12 October 2023