

**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 SUBSTANCES

Each Lyophilisate vial contains:

Marbofloxacin200mg

Each Solvent vial contains:

Water for injections20mL

Each ml of Reconstituted solution contains:

Marbofloxacin10.00mg

3.PACKAGE SIZE

2 vials of 20ml.

4.TARGET SPECIES

Dogs and cats.

5. INDICATION(S)

In **dogs**, the veterinary medicinal product is indicated:

- in the treatment of infected wounds and subcutaneous abscesses 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**, the veterinary medicinal product is indicated:

- in the treatment of infected wounds and subcutaneous abscesses due to Pasteurella multocida, Staphylococcus intermedius, Staphylococcus aureus,

Staphylococcus

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

6.ROUTES OF ADMINISTRATION

Solution for injection

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.

7.WITHDRAWAL PERIODS

Not applicable

8.EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within: 28 days

Once reconstituted, use by:

9.SPECIAL STORAGE PRECAUTIONS

Powder and Solvent: Do not store above 25°C. Protect from light.

Reconstituted solution: Do not store above 25°C. Protect from light.

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

Vetoquinol UK Limited

14.MARKETING AUTHORISATION NUMBER

Vm 08007/5039

15.BATCH NUMBER

Lot {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 SUBSTANCES

Each Lyophilisate vial contains:
Marbofloxacin200mg

3.TARGET SPECIES

Dogs and cats.

4.ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5.WITHDRAWAL PERIODS

6.EXPIRY DATE

Exp {mm/yyyy}

Once reconstituted use within: 28 days.
Once reconstituted use by:

7.SPECIAL STORAGE PRECAUTIONS

Powder and reconstituted solution: Do not store above 25°C.
Protect from light.

8.NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

9.BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {solvent vial, 20ml}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for use with Marbocyl SA 200mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Marbocyl SA 200 mg Powder and Solvent for Solution for Injection

2. Composition

Each Lyophilisate vial contains:

Active substance:
Marbofloxacin 200mg

Excipients:
Disodium edetate 20mg
Benzalkonium chloride 2mg

Each solvent vial contains:

Water for injections20mL

Reconstituted solution:

Each ml contains:

Active substances:
Marbofloxacin10.00mg

Excipients:
Disodium edetate1.0mg
Benzalkonium chloride.....0.1mg

White freeze-dried powder and clear, colourless solvent for solution for injection.
The reconstituted solution is clear to greenish yellow.

3. Target species

Dogs and cats.

4. Indications for use, specifying the target species

In dogs, the veterinary medicinal product is indicated:

- in the treatment of infected wounds and subcutaneous abscesses 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, the veterinary medicinal product is indicated:

- in the treatment of infected wounds and subcutaneous abscesses due to Pasteurella multocida, Staphylococcus intermedius, Staphylococcus aureus, Staphylococcus spp., Enterobacter spp. and Klebsiella spp.

Marbofloxacin is inactive against anaerobic bacteria.

5. 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.

6. Special warnings

Special precautions for safe use in the target species:

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.

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 slight irritation.

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

Wash hands after use.

Pregnancy:

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.

Interaction with other medicinal products and other forms of interaction:

The dosage of theophylline must be reduced when used concurrently.

Overdose:

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

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:

See section 6 'Special precautions for safe use in the target species'

7. Adverse events

Cats and Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs ¹ ; Seizure ¹ ; Ataxia ¹ ; Mydriasis ¹ ; Muscle tremor ¹ Hypersalivation ; emesis ; Injection site reaction.
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¹ In severe cases, symptomatic treatment should be administered.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.

Before reconstitution:

Do not store above 25°C.

Protect from light.

After reconstitution:

Do not store above 25°C.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions:28 days.

12. Special precautions for disposal

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 applicable national collection systems. 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 NUMBER AND PACK SIZES

Vm 08007/5039

Powder: Amber type II glass vial closed with rubber stopper and aluminium seal.
Solvent: Colourless type II glass vial closed with rubber stopper and aluminium seal.
Cardboard box with 1 glass vial of powder and 1 glass vial of solvent.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

Tel: (+44)1280 814500

Manufacturer responsible for batch release:
Vetoquinol SA
Magny-Vernois
70200 Lure
France

17. Other information

POM-V

Gavin Hall
Approved: 11 November 2025