SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL SA 200 mg powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lyophilisate vial contains:

Active substance:
Marbofloxacin 200mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Disodium edetate	20mg
Benzalkonium chloride	2mg
Mannitol	
Sodium Hydroxide	

Each solvent vial contains:
Water for injections.....20mL

Reconstituted solution:
Each ml contains:

Active substances:
Marbofloxacin.....10.00mg

Excipients:

Qualitative composition of excipients and other constituents	*Quantitative composition if that information is essential for proper administration of the veterinary medicinal product*
Disodium edetate	*1.0mg*
Benzalkonium chloride	*0.1mg*
Mannitol	
Sodium Hydroxide	
Water for Injections	

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

3. CLINICAL INFORMATION

3.1 Target species

- DOGS
- CATS

3.2 Indications for use for each target species

In dogs, Indicated:

- in the treatment of infected wounds and subcutaneous abscesses due to *Staphylococcus intermedius*, *Staphylococcus aureus*, *Escherichia coli*, *Pasteurella sp*. and *Pseudomonas sp*.
- in the treatment of lower or urinary tract infections due to *Escherichia coli and Proteus sp.*

In cats, Indicated:

- in the treatment of infected wounds and subcutaneous abscesses due to *Pasteurella multocida, Staphylococcus intermedius*, *Staphylococcus aureus*, *Staphylococcus sp., Enterobacter sp. and Klebsiella sp.* Marbofloxacin is inactive against anaerobic bacteria.

3.3 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.

3.4 Special warnings

None

3.5 Special precautions for use

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 (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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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.

[1] In severe cases, symptomatic treatment should be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

3.8 Interaction with other medicinal products and other forms of interaction

The dosage of theophylline must be reduced when used concurrently.

3.9 Administration routes and dosage

Reconstitution:- Before use, reconstitute the 4yophilized 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 4yophilized powder. When reconstituted in this way, the solution will contain 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/kg (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.

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

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

3.11 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 3.5 ‘Special precautions for use’.

3.12 Withdrawal period(s)

Not Applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code: QJ01MA93

4.2 Pharmacodynamics

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, Shigella spp, Actinobacillus pleuropneumoniae, Bordetella bronchiseptica, Mannheumia haemolytica, Pasteurella multocida, Klebsiella spp, Haemophilus spp, Moraxella spp, Pseudomonas spp*, *Brucella canis*) as well as Mycoplasma.

4.3 Pharmacokinetics

After subcutaneous administration at the recommended dose of 2mg/kg to dogs and cats, marbofloxacin is rapidly absorbed with a bioavailability 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 (< 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 with an elimination half life from 10 to14 h in both species, mainly in the active form in urine (2/3), and faeces (1/3).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known

5.2 Shelf life

- Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
- Shelf life after reconstitution according to direction: 28 days.

5.3 Special precautions for storage

Before reconstitution:
Do not store above 25°C.
Protect from light.

After reconstitution:
Do not store above 25°C.
Protect from light.

5.4 Nature and composition of immediate packaging

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.

Pack size: One vial of powder and one vial of solvent.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/5039

8. DATE OF FIRST AUTHORISATION

08 March 1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2025

10. CLASSIFICATION OF THE VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 11 November 2025