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

Lyophilisate vial Active ingredient:	
Marbofloxacin	200mg
Antimicrobial preservatives:	
Disodium edetate	20mg
Benzalkonium chloride	2mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

- DOGS
- CATS

4.2 Indications for use, specifying the 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.

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

None

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 (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.

4.6 Adverse reactions (frequency and seriousness)

After subcutaneous administration, no undesirable effect is observed up to 2 times the maximum recommended therapeutic dose in dogs or 3 times the maximum recommended dose for cats.

After i.v. administration at 4mg/kg, rare mild and transitory side effects have been reported:

- ptyalism (excess salivation)
- nervous disorders: vocalization, excitation, 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 lyophilised 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 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.

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

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

Pharmacokinetic properties

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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate dihydrate Benzalkonium chloride Mannitol
Sodium hydroxide Water for injection

6.2 Incompatibilities

None

6.3 Shelf life

- 3 years.

- The reconstituted solution should be stored below 25°C and protected from light. Any reconstituted product remaining 28 days after preparation should be discarded.

6.4 Special precautions for storage

Protect both lyophilised powder and reconstituted solutions from light. Do not store above 25°C.

6.5 Nature and composition of immediate packaging

MARBOCYL SA 200mg, is packaged in amber Type II glass vials containing 200mg marbofloxacin in the form of a white freeze dried power. Colourless Type II glass vials of solvent are supplied which contain 20ml Water for Injections PhEur.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

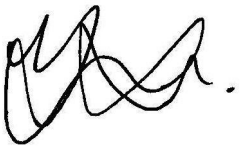
Vm 08007/4079

9. DATE OF FIRST AUTHORISATION

08 March 1999

10. DATE OF REVISION OF THE TEXT

October 2023



Approved: 12 October 2023