

## **Part II**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### **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

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 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.

##### **4.4 Special warnings for each target species**

None

#### **4.5 Special precautions for use**

##### **(i) Special precautions for use in animals**

None.

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

People with known hypersensitivity to fluoroquinolones should avoid using this product.  
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).

#### **4.7 Use during pregnancy and lactation**

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*, *Mannheimia 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 (T<sub>1/2</sub>) 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 to 14 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**

Vétoquinol UK Limited  
Vetoquinol House  
Great Slade  
Buckingham Industrial Park  
Buckingham  
MK18 1PA

### **8. MARKETING AUTHORISATION NUMBER(S)**

Vm 08007/4079

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

08 March 1999 /08 March 2009

### **10. DATE OF REVISION OF THE TEXT**

August 2007