

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Marbocyl 10% Solution for Injection

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Marbofloxacin	10.0g
Monothioglycerol	0.1g
Metacresol	0.2g
Disodium edetate	0.01g

For a full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Solution for Injection.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle & pigs.

#### **4.2 Indications for use, specifying the target species**

In cattle: Indicated in the treatment of respiratory infections caused by susceptible strains of organisms. It is also indicated in the treatment of acute E. coli mastitis.

In pigs: Indicated in the treatment of Metritis Mastitis Agalactia syndrome caused by susceptible strains of organisms.

#### **4.3 Contra-indications**

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 quinolone 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

Official and local antimicrobial policies should be taken into account when the product is used. 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. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

- 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)**

Intramuscular or subcutaneous injections are well tolerated although in very rare cases transitory inflammatory lesions can occur at the injection site.

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**

May be used in pregnant and lactating cows and sows.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None

#### **4.9 Amounts to be administered and administration route**

The recommended dosage is 2mg/kg/day (1ml/50kg) in a single daily injection by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.

Treatment durations are 3 days in pigs and 3 to 5 days in cattle.

In order to reduce the risk of particulate contamination of the product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.

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

Overdosage may cause acute signs in the form of neurological disorders which would have to be treated symptomatically.

No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively.

#### 4.11 Withdrawal period(s)

	Meat	Milk
Cattle	6 days	36 hours
Pigs	4 days	

### 5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QJ01MA93

#### Pharmacodynamic properties:

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. It is effective against a wide range of Gram positive bacteria (in particular *Staphylococci*) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Citrobacter freundii*, *Enterobacter cloacae*, *Serratia marcescens*, *Morganella morganii*, *Proteus spp*, *Klebsiella spp*, *Shigella spp*, *Pasteurella spp*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas spp*) as well as *Mycoplasma spp*.

#### Pharmacokinetic properties:

After subcutaneous or intramuscular administration in cattle and intramuscular administration in pigs at the recommended dose of 2mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5µg/ml within less than 1 hour. Its bioavailability is close to 100%.

It is weakly bound to plasma proteins (less than 10% in pigs and 30% in cattle), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, uterus, digestive tract) it achieves a higher concentration than in plasma.

In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves ( $t_{1/2} \beta = 5-9h$ ) but faster in ruminant cattle ( $t_{1/2} \beta = 4-7h$ ) predominantly in the active form in urine (3/4 in pre-ruminating calves, 1/2 in ruminants) and faeces (1/4 in pre-ruminating calves, 1/2 in ruminants).

In pigs, marbofloxacin is eliminated slowly ( $t_{1/2} \beta = 8-10h$ ) predominantly in the active form in urine (2/3) and faeces (1/3)

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Monothioglycerol  
Metacresol  
Disodium edetate  
Gluconolactone  
Water for injections

### **6.2 Incompatibilities**

Nil

### **6.3 Shelf life**

3 Years

Following withdrawal of the first dose, use the product within 28 days.  
Any unused material should be discarded.

### **6.4 Special precautions for storage**

Do not store above 25°C. Protect from light.

### **6.5 Nature and composition of immediate packaging**

Marbocyl 10% is packaged in amber type II glass vials of 20ml, 50ml, 100ml and 250ml.

The vials are closed with a chlorobutyl rubber stopper oversealed with aluminium caps.  
Each vial is packaged in a cardboard box.

### **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.

Manure and slurry containing marbofloxacin should not be spread on the same area of land in successive years.

**7. MARKETING AUTHORISATION HOLDER**

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

**8. MARKETING AUTHORISATION NUMBER**

Vm 08007/4149

**9. DATE OF FIRST AUTHORISATION**

14 February 1997

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

September 2023

Approved 21 September 2023

