

**Part II**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

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

MARBOCYL 2 % SOLUTION FOR INJECTION

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Marbofloxacin	2.0 % w/v
Disodium edetate	0.1 % w/v
Thioglycerol	0.5 % w/v
Metacresol	2.0 % w/v

For a full list of excipients, see section 6.1

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. CLINICAL PARTICULARS**

**4.1 Target species**

- Cattle : pre-ruminants up to 100 kg b.w.

- Pigs

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

In cattle and pigs

Indicated in the treatment of respiratory infections caused by susceptible strains of organisms.

**4.3 Contra-indications**

None

**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. These inclusions of prudent guidance are as specified in EMEA/CVMP/416168/2006-FINAL, issued 8 November 2006.

**(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)**

No severe side-effects are to be expected at doses up to 5 times the recommended dose in cattle and pigs. In particular no lesions of the articular joints are encountered.

Subcutaneous injection is well tolerated. Transitory inflammatory reactions are sometimes observed at the injection site, but without clinical impact.

**4.7 Use during pregnancy, lactation or lay**

Not applicable.

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

None known

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

The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.

Treatment duration is as follows :

- cattle, IV route : 3 to 5 days
- cattle, SC route : 3 days
- pigs, IM route : 3 to 5 days

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 should be treated symptomatically.

**4.11 Withdrawal period(s)**

	<b>MEAT</b>
Preruminating calves (up to 100kg bodyweight)	6 days
Pigs	2 days

The volume of injection should be limited to 10 ml at each site of injection for pigs.

## 5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code:QJ01MA93

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*, *Pasteurella multocida*, *Pasteurella haemolytica* and *Actinobacillus pleuropneumoniae*) as well as *Mycoplasma* (*Mycoplasma bovis*, *Mycoplasma hyopneumoniae*).

Resistance to *Streptococcus* may occur.

*Salmonella typhimurium*, *Campylobacter jejuni*, *Citrobacter*, *Enterobacter*, *Proteus spp*, *Klebsiella spp*, *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica*, *Pasteurella haemolytica*, *Pasteurella multocida*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas aeruginosa*) as well as *Mycoplasma* (*Mycoplasma bovis*, *Mycoplasma dispar*, *Mycoplasma hyopneumoniae*).

### Pharmacokinetic properties :

After subcutaneous administration in cattle and pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and 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 higher concentrations than in plasma.

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

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

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Gluconolactone  
Water for injection  
Mannitol

### 6.2 Incompatibilities

Nil

### 6.3 Shelf life

2 years  
Following withdrawal of the first dose, use the product within 28 days

Discard unused material.

### 6.4. Special precautions for storage

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

**6.5 Nature and composition of immediate packaging**

Packaged in amber type II glass vials of 10, 20, 50 ml, 100 ml and 250 ml.  
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 SA  
Magny- Vernois  
BP 189  
70204 LURE Cedex  
FRANCE

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

Vm 06462/4005

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

25 June 1998/26 June 2003

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

May 2007