# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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|---|---|
| The UK, Ireland, | Marbocyl Solo 10% solution for injection for cattle |
| Spain | Marbocyl Bovinos 100 mg/ml solution for injection for cattle |
| Germany, Austria, The Netherlands, Belgium, Italy, Poland, Portugal, The Slovak Republic, The Czech Republic, Greece, Luxembourg, France | Marbocyl S 10% solution for injection |

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance :
Marbofloxacin .....100.0 mg

Excipients :
Disodium edetate.....0.1 mg
Thioglycerol .....1.0 mg
metacresol .....2.0 mg

For a full list of excipients, see section 6.1."

## 3. PHARMACEUTICAL FORM

Solution for injection.
Yellow greenish to yellow brownish, clear solution.

## 4. CLINICAL PARTICULARS

### 4.1 TARGET SPECIES

Cattle

### 4.2. INDICATIONS FOR USE, SPECIFYING THE TARGET SPECIES

Therapeutic treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni*.

### 4.3 CONTRA-INDICATIONS

Do not use in animals with known hypersensitivity to fluoroquinolones.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

### 4.4 SPECIAL WARNING 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 medicinal product to animals

People with known hypersensitivity to quinolones should avoid any contact with the product.
If the product comes into contact with the skin or eyes, rinse with copious amounts of water.
Accidental self-injection can induce a slight irritation.

## 4.6 ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.
Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which may persist for at least 12 days after injection. No other adverse effect was observed on cattle.

## 4.7 USE DURING PREGNANCY, LACTATION OR LAY

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin. Safety of the product at 8 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

## 4.8 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

None known

## 4.9 AMOUNT(S) TO BE ADMINISTERED AND ADMINISTRATION ROUTE

The recommended dosage is 8 mg/kg body weight i.e. 2 ml /25kg body weight in a single intramuscular injection
If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

### 4.10 OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES), IF NECESSARY

No sign of overdosage has been observed after administration of 3 times the recommended dose. Overdosage may cause signs such as acute neurological disorders which should be treated symptomatically.

### 4.11 WITHDRAWAL PERIOD(S)

Meat and offal: 3 days
Milk : 72 hours

## 5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QJ01MA93
Pharmacotherapeutic group: anti-infectives for systemic use

### 5.1 PHARMACODYNAMIC PROPERTIES

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group, which acts by inhibition of DNA gyrase. It has a broad-spectrum activity *in vitro* against Gram-positive and Gram-negative bacteria.
The marbofloxacin *in vitro* activity against pathogens isolated in 2004 from bovine respiratory diseases during a clinical field trial in France, Germany, Spain and Belgium, is good: MIC values are comprised between 0.015 and 0.25 µg/ml for *M. haemolytica* ($MIC_{90}$ = 0.124 µg/ml; $MIC_{50}$ = 0.025 µg/ml), between 0.004 and 0.12 µg/ml for *P. multocida* ($MIC_{90}$ = 0.022 µg/ml; $MIC_{50}$ = 0.009 µg/ml) and between 0.015 and 2 µg/ml for *Histophilus somni*. Strains with MIC ≤ 1 µg/ml are sensitive to marbofloxacin whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin.
Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

### 5.2 PHARMACOKINETIC PARTICULAR

After a single intramuscular administration in cattle at the recommended dose of 8 mg/kg, the maximum plasma concentration of marbofloxacin (Cmax) is 7.3 µg/ml reached in = 0.78h (Tmax). Binding to plasma proteins is about 30%. Marbofloxacin is eliminated slowly ($T1/2\beta$ = 15.60 h), predominantly in the active form in urine and faeces.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 LIST OF EXCIPIENTS

Disodium edetate
Thioglycerol
metacresol
Gluconolactone
Water for injection

### 6.2 INCOMPATIBILITIES

Do not mix with other medicinal products

### 6.3 SHELF-LIFE

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

### 6.4 SPECIAL PRECAUTIONS FOR STORAGE

Protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

### 6.5 NATURE AND COMPOSITION OF IMMEDIATE PACKAGING

Details of the primary packaging:
Amber type II glass vials
Type I chlorobutyl rubber stopper

Presentations:
Carton containing one 50 ml vial
Carton containing one 100 ml vial
Carton containing one 250 ml vial

Not all pack sizes may be marketed.

### 6.6 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS, IF APPROPRIATE

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

Vm 08007/4118

## 9. DATE OF FIRST AUTHORISATION

14 March 2007

## 10. DATE OF REVISION OF THE TEXT

May 2011