# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl 10% Solution for Injection for cattle and pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substances:**
Marbofloxacin 100.0 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Monothioglycerol | 1.0 mg |
| Metacresol | 2.0 mg |
| Disodium edetate Dihydrate | 0.1 mg |
| Gluconolactone | |
| Water for injections | |

Clear, yellow greenish to yellow brownish solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle & pigs.

### 3.2 Indications for use for each 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.

## 3.3 Contraindications

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.

## 3.4 Special warnings

None.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to (fluoro)quinolones, such as marbofloxacin, should avoid contact with this veterinary medicinal 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 package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:

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

## 3.6 Adverse events

Cattle and swine:

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Injection site inflammation[1] |

[1] Transitory

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

May be used in pregnant and lactating cows and sows.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

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 veterinary medicinal product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Cattle
Meat and offal: 6 days
Milk: 36 hours

Pigs
Meat and offal: 4 days

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QJ01MA93

### 4.2 Pharmacodynamics

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*.

### 4.3 Pharmacokinetics

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 ($t_{½}$ β = 5-9h) but faster in ruminant cattle ($t_{½}$ β = 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 ($t_{½}$ β = 8-10h) predominantly in the active form in urine (2/3) and faeces (1/3)

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

### 5.2 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

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

The veterinary medicinal product 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.

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

## 7. MARKETING AUTHORISATION NUMBER

Vm 06462/3023

## 8. DATE OF FIRST AUTHORISATION

14 February 1997

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2026

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

*Gavin Hall*

Approved: 15 July 2026