1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl 100 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Marbofloxacin 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
m-Cresol	2.0 mg
Monothioglycerol	1.0 mg
Disodium Edetate	0.1 mg
Water for injection	Excipient Q.S. 1 ml
Gluconolactone	

Clear, yellow to green/brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

In Cattle
The veterinary medicinal product is 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
The veterinary medicinal product is indicated in the treatment of Metritis Mastitis Agalactia syndrome caused by susceptible strains of organisms.

3.3 Contraindications

None.

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 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:

Not applicable.

3.6 Adverse events

Cattle and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain. Injection site inflammation[1]

[1] Without clinical impact.

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 its local representative 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:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cattle: intramuscular, subcutaneous or intravenous injection.
Pigs: Intramuscular injection.

The recommended dosage is 2 mg/kg (1 ml/50 kg) 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.

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 to be expected at doses up to 3 to 5 times the recommended dose in cattle and pigs respectively. In particular no lesions of the articular joints are encountered.

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: 4 days.
Milk: 24 hours.

Pigs:
Meat and offal: 2 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, Streptococci) 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, *Brucella canis*) as well *Mycoplasma* spp. It should be noted that some strains of Streptococci, *Pseudomonas* and *Mycoplasma* may not be sensitive to Marbofloxacin.

4.3 Pharmacokinetics

After subcutaneous or intramuscular administration in cattle and pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 microgram/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 higher concentrations than in plasma.

In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves (t½β=5-9 hours) but faster in ruminant cattle (t½β =4-7 hours) 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 (t½β 8-10 hours) 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: 36 months.

Shelf life after first opening the immediate packaging: 1 month.

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 10, 20, 50, 100 and 250 ml.

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 or household waste.

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

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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10983/034/001

8. DATE OF FIRST AUTHORISATION

31/10/1997

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

12/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).