Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl 10 % Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Marbofloxacin	100 mg

Excipients:

m-Cresol	2.0 mg
Monothioglycerol	1.0 mg
Disodium Edetate	0.1 mg
Excipient Q.S.	1 ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, yellow to green/brown solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and pigs

4.2 Indications for use, specifying the target species

In Cattle
Marbofloxacin 10% injection 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
Marbofloxacin 10% injection is indicated in the treatment of Metritis Mastitis Agalactia syndrome caused by susceptible strains of organisms

4.3 Contraindications

None known

4.4 Special warnings for each target species

None known

4.5 Special precautions for use

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 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

None

4.6 Adverse reactions (frequency and seriousness)

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.

Occasionally, the subcutaneous and intramuscular use of the product in cattle may be associated with pain and localized inflammatory reaction without clinical impact

4.7 Use during pregnancy, lactation or lay

Marbofloxacin may be used in pregnant and lactating cows and sows.

4.8 Interaction with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

The recommended dosage is 2 mg/kg (1ml/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

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

4.11 Withdrawal period(s)

	Meat	**Milk**
Cattle	4 days	24 hours
Pigs	2 days	

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet Code: QJ01MA93 Fluoroquinolones

5.1 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, 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

5.2 Pharmacokinetic particulars

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 h) but faster in ruminant cattle (t½β =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 (t½β 8-10h) predominantly in the active form in urine (2/3) and faeces (1/3).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gluconolactone
Disodium Edetate
Monothioglycerol
m-Cresol
Water for injection

6.2 Major incompatibilities

None known

6.3 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

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 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

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

Any unused product or waste material should be disposed of in accordance with national requirements.
Manure containing marbofloxacin should not be spread on the same area of land in successive years.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 October 1997
Date of last renewal: 30 October 2007

10 DATE OF REVISION OF THE TEXT

August 2019