SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL 10% SOLUTION FOR INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Marbofloxacin	10.0g
Monothioglycerol	0.1g
Metacresol	0.2g
Disodium edetate	0.01g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle & pigs.

4.2 Indications for use, specifying the 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.

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.

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 3 or 5 times the recommended dose in cattle and pigs respectively. In particular, no lesions of the articular joints are encountered.

Intramuscular or subcutaneous injections are well tolerated although transitory inflammatory lesions without clinical impact can occur at the injection site.

4.7 Use during pregnancy, lactation or lay

May be used in pregnant and lactating cows and sows.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

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 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 would have to be treated symptomatically.

4.11 Withdrawal period(s)

	Meat	Milk
Cattle	6 days	36 hours

Pigs	4 days	

5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QJ01MA93

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*) 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*.

Pharmacokinetic properties:

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monothioglycerol
Metacresol
Disodium edetate
Gluconolactone
Water for injections

6.2 Incompatibilities

Nil

6.3 Shelf life

3 years

Following withdrawal of the first dose, use the product within 28 days.
Any unused material should be discarded.

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 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.

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 UK Limited
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NN12 7LS
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8. MARKETING AUTHORISATION NUMBER

Vm 08007/4149

9. DATE OF FIRST AUTHORISATION

14 February 1997

10. DATE OF REVISION OF THE TEXT

August 2018

Approved: 31 August 2018