SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL 2 % SOLUTION FOR INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Marbofloxacin	2.0 % w/v
Disodium edetate	0.01 % w/v
Thioglycerol	0.05 % w/v
Metacresol	0.2 % w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

- Cattle: pre-ruminants up to 100 kg b.w.

- Pigs

4.2 Indications for use, specifying the target species

In cattle and pigs
Indicated in the treatment of respiratory infections 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 5 times the recommended dose in cattle and pigs. In particular no lesions of the articular joints are encountered.

Subcutaneous injection is well tolerated. Transitory inflammatory reactions are sometimes observed at the injection site, but without clinical impact.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.

Treatment duration is as follows:

- cattle, IV route : 3 to 5 days
- cattle, SC route : 3 days
- pigs, IM route : 3 to 5 days

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 should be treated symptomatically.

4.11 Withdrawal period(s)

	MEAT
Preruminating calves (up to 100kg bodyweight)	6 days
Pigs	4 days

The volume of injection should be limited to 10 ml at each site of injection for pigs.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code:QJ01MA93

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,Campylobacter jejunii, Citrobacter, Enterobacter, Proteus* spp*, Klebsiella* spp, *Actinobacillus pleuropneumoniae, Bordetella bronchiseptica, Pasteurella haemolytica, Pasteurella multocida, Haemophilus spp, Moraxella* spp*, Pseudomonas aeruginosa*) as well as Mycoplasma *(Mycoplasma bovis, Mycoplasma dispar, Mycoplasma hyopneumoniae).*

Resistance to Streptococcus spp. may occur.

Pharmacokinetic properties:

After subcutaneous administration in cattle and pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and 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 ($t_{1/2}\beta$ = 5-9 h) predominantly in the active form in urine (3/4) and faeces (1/4).

In pigs, marbofloxacin is eliminated slowly ($t_{1/2}\beta$ = 8-10 h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gluconolactone
Water for injection
Mannitol

6.2 Incompatibilities

Nil

6.3 Shelf life

2 years
Following withdrawal of the first dose, use the product within 28 days

Discard unused material.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Packaged in amber type II glass vials of 10, 20, 50 ml, 100 ml and 250 ml.
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 08007/4148

9. DATE OF FIRST AUTHORISATION

25 June 1998

10. DATE OF REVISION OF THE TEXT

August 2018

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