Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl 2 %w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Marbofloxacin	20.0	mg

Excipients

Metacresol	2.0	mg
Monothioglycerol	0.5	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A yellow-greenish to yellow-brownish solution

4 CLINICAL PARTICULARS

4.1 Target Species

Pre- ruminating and ruminating calves and pigs

4.2 Indications for use, specifying the target species

In Calves
Marbofloxacin 2% is indicated in the treatment of respiratory infections caused by susceptible strains of organisms.

In Pigs
Marbofloxacin 2% is indicated in the treatment of respiratory infections caused by susceptible strains of organisms and in the treatment of Metritis Mastitis Agalactia (MMA) syndrome caused by susceptible strains of organisms.

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

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 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
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 calves and pigs respectively. In particular no lesions of the articular joints are encountered.

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

4.7 Use during pregnancy, lactation or lay

Marbofloxacin may be used in pregnant and lactating sows.

4.8 Interaction with other medicinal products and other forms of interactions

Not applicable.

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 intramuscular, subcutaneous or intravenous routes in calves and by intramuscular route in pigs. Treatment durations are 3 to 5 days in calves and pigs.

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)

Calves
Meat and offal: 4 days
Milk: Not applicable

Pigs
Meat and offal: 2 days.
Milk: Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones
ATC Vet code: QJ01MA93

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, Campylobacter jejunii, Citrobacter freundii, Enterobacter cloacae, Serratia marcescens, Morganella morganii, Proteus* spp*, Klebsiella* spp*, Shiegella* spp*, Actinobacillus pleuropneumoniae, Bordetella bronchiseptica, Pasteurella* spp*, Haemophilus* spp*, Moraxella* spp*, Pseudomonas* spp*, Brucella canis*) as well as *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 micrograms/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 (t½ = 5-9 h) but faster in ruminant cattle (t½ = 4-7 h) 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 (t½ 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
Disodium edetate
Mannitol
Monothioglycerol
Metacresol
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 1 month

6.4 Special precautions for storage

Store below 25°C and protect from light.

6.5 Nature and composition of immediate packaging

Marbocyl 2% injection is packaged in amber type II glass vials of 10, 20, 50 and 100ml.
The vials are closed with a chlorobutyl rubber stopper and 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.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/032/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 September 1998
Date of last renewal: 17 September 2008

10 DATE OF REVISION OF THE TEXT

August 2019