1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl 20 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:

Marbofloxacin…….20.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Metacresol	2.0 mg
Monothioglycerol	0.5 mg
Gluconolactone	
Disodium edetate	
Mannitol	
Water for injections	

A yellow-greenish to yellow-brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Pre-ruminating and ruminating calves and pigs.

3.2 Indications for use for each target species

In calves:
The veterinary medicinal product is indicated in the treatment of respiratory infections caused by susceptible strains of organisms.

In pigs:
The veterinary medicinal product 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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Calves and pigs:

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

[1] Following subcutaneous or intramuscular use, 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 in pregnant and lactating sows.

3.8 Interaction with other medicinal products and other forms of interaction

Not applicable.

3.9 Administration routes and dosage

Calves: Intramuscular use, subcutaneous use or intravenous use.
Pigs: Intramuscular use.

The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection. Treatment durations are 3 to 5 days in calves and pigs.

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.

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

Calves
Meat and offal: 4 days.
Milk: Not applicable.

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

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, 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.

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 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 hours) but faster in ruminant cattle (t½ = 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 (t½ 8-10 hours) predominantly in the active form in urine (2/3) and faeces (1/3).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3. Special precautions for storage

Store below 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 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.

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

Medicines should not be disposed of via wastewater or household waste.

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)

VPA10983/032/001

8. DATE OF FIRST AUTHORISATION

18 September 1998

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

18 October 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).