SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl 160 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Marbofloxacin.....160 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	15 mg
Glucono-delta-lactone	
Water for injection	

Clear yellow greenish to yellow brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

In cattle:
- Therapeutic treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida* and *Mannheimia haemolytica*.

In lactating cows:
- Treatment of acute mastitis caused by sensitive strains of *Escherichia coli.*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other fluoroquinolones or to any of the excipients.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

3.4 Special warnings

The efficacy of the veterinary medicinal product has not been tested on mastitis caused by Gram positive bacteria.

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 this veterinary medicinal 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. Wherever possible, use of the veterinary medicinal product should only be based on susceptibility testing.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Wash hands after use.

In case of contact with skin or eyes, rinse with plenty of water.

Care should be taken to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the label or the package leaflet to the physician.

Accidental self-injection can induce a slight irritation
Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction (e.g pain, swelling)[1] Arthropathy[2] Anaphylactic-type reaction[3]

[1] Transient reaction if injected intramuscularly. May persist up to 7 days after injection.
[2] Such lesions were observed in cattle after a three days treatment. These lesions did not induce clinical signs and should be reversible, particularly if they were to be observed after a single administration.
[3] With a potentially fatal outcome.

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 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:

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Safety of the product at 10 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular or intravenous use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Where there is slight cloudiness or visible particles present, such cloudiness or particles disappear when the bottle is shaken before use.

- Therapeutic treatment of respiratory infections

10 mg/kg body weight i.e. 10 ml /160 kg body weight in a single intramuscular injection.

- Treatment of acute mastitis caused by sensitive strains of *Escherichia coli*

10 mg/kg body weight i.e. 10 ml/160 kg body weight in a single intramuscular or intravenous injection.

If the volume to be injected intramuscularly is more than 20 ml, it should be divided between two or more injection sites.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Lesions of the joint cartilage were observed in some animals treated at 10 mg/kg or 30 mg/kg for three times the recommended treatment duration, but did not induce clinical signs. Moreover, no other signs of overdosage was observed throughout this study.
Overdosage may cause signs such as acute neurological disorders which should 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

Meat and offal: 5 days.
Milk: 48 hours.

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. The *in vitro* activity of marbofloxacin has been demonstrated towards *Pasteurella multocida*, *Mannheimia haemolytica* and *Escherichia coli.*
The marbofloxacin *in vitro* activity against pathogens isolated in 2007 from bovine respiratory diseases is good: MIC values are comprised between 0.008 and 0.5 µg/ml for *M. haemolytica* (MIC_{90} = 0.139 µg/ml; MIC_{50} = 0.021 µg/ml), between 0.004 and 0.5 µg/ml for *P. multocida* (MIC_{90} = 0.028 µg/ml; MIC_{50} = 0.012 µg/ml).
In 2008, the marbofloxacin MIC_{50} for *E. coli* isolated from bovine mastitis was 0.021 µg/ml and the MIC_{90} was 0.038 µg/ml.
Strains with MIC ≤ 1 µg/ml are sensitive to marbofloxacin whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin.
Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

4.3 Pharmacokinetics

After a single intramuscular administration in cattle at the recommended dose of 10 mg/kg body weight, the maximum plasma concentration of marbofloxacin (Cmax) is 7.915 µg/ml reached in 1.28 h (Tmax) for an exposure (AUC_{INF}) of 52.7 µg.h/mL. Bioavailability after intramuscular injection is complete (more than 90%). Marbofloxacin is extensively distributed. Binding to plasma proteins is about 30 %.
After intravenous or intramuscular administration, marbofloxacin concentrations in milk increase rapidly and the AUC_{INF} , Tmax and Cmax values obtained in plasma and milk after both administration routes are similar.
Marbofloxacin is eliminated slowly (T1/2λz = 17.50 h) predominantly as the active form in urine and faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with 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: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Amber type II glass vials
Chlorobutyl rubber stopper
Aluminium cap or flip cap

Pack sizes:

Cardboard box containing one 50 ml vial.
Cardboard box containing one 100 ml vial.
Cardboard box containing one 250 ml vial.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/5060

8. DATE OF FIRST AUTHORISATION

25 July 2011

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

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 12 December 2025