PARTICULARS TO APPEAR ON THE OUTER PACKAGE:
Cardboard box of 50 ml / 100 ml / 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl 160 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin ……160 mg/ml

3. PACKAGE SIZE

50 mL
100 mL
250 mL

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 5 days.

Milk: 48 hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days, by:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

14. MARKETING AUTHORISATION NUMBER

Vm 08007/4130

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE:
Label of 100 (and 250 ml) vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

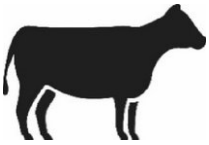
Forcyl 160 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin ……160 mg/ml

3. TARGET SPECIES

Cattle.



4. ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

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

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days, by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

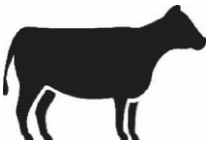
9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS: Label of 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl 160 mg/ml



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Marbofloxacin 160 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days, by:

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Forcyl 160 mg/ml solution for injection for cattle

2. Composition

Each ml contains:

Active substance:

Marbofloxacin .....160 mg

Excipient:

Benzyl alcohol (E1519)….....15 mg

Clear yellow greenish to yellow brownish solution.

3. Target species

Cattle.

4. Indications for use

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.*

5. 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).

6. Special warnings

Special warnings:

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

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.
In case of contact with skin or eyes, rinse with plenty of water. Care should be taken to avoid accidental self-injection.
Accidental self-injection can induce a slight irritation.
In case of accidental self-injection, seek medical advice immediately and show the label or the package leaflet to the physician.
Wash hands after use.

Pregnancy and lactation:

Use only according 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.

Studies in laboratory animals (rats, rabbits) did not show any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

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

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site reaction (e.g pain, swelling)[1]
Arthropathy (disease of a joint)[2]
Anaphylactic-type reaction (severe allergic 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

None.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08007/4130

Cardboard box with 1 vial of 50 ml:
Cardboard box with 1 vial of 100 ml:
Cardboard box with 1 vial of 250 ml:

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
Telephone: (+44) 1280 814 500

Manufacturer responsible for batch release:

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Or

Vetoquinol Biowet Sp.z.o.o
ul. Kosynierów Gdyńskich 13-14
66-400 Gorzów Wielkopolski
Poland

17. Other information

POM-V

Gavin Hall
Approved: 15 August 2025