ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
BOX OF 50 ml / 100 ml / 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl 160 mg/ml solution for injection for cattle
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Marbofloxacin ……160 mg
Benzyl alcohol (E 1519) ……15 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle.

6. INDICATIONS

Not included.

7. METHOD AND ROUTES OF ADMINISTRATION

10 mg/kg i.e. 10 ml/160 kg
Intramuscular or intravenous route
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS

The sentence “Read the package leaflet before use” is already included under section 7.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Not applicable.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4130

17. MANUFACTURER'S BATCH NUMBER

Batch {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 for cattle
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin ……160 mg/ml
Benzyl alcohol **(E 1519)** ……15 mg/ml

3. PHARMACEUTICAL FORM

Not requested.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle.

6. INDICATIONS

Not requested.

7. METHOD AND ROUTES OF ADMINISTRATION

10 mg/kg i.e. 10 ml/160 kg
Intramuscular or intravenous route.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS

The sentence “Read the package leaflet before use” is already included under section 7.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Not applicable.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4130

17. MANUFACTURER'S BATCH NUMBER

Batch {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 solution for injection for cattle
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE

Marbofloxacin 160 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml.

4. ROUTES OF ADMINISTRATION

IM or IV
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days.
Once broached, use by:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET
Forcyl 160 mg/ml, solution for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE , IF DIFFERENT

Marketing Authorisation Holder:

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:

Vetoquinol SA
Magny vernois
70200 Lure
FRANCE

Or

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl 160 mg/ml solution for injection for cattle
Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One ml contains:
Marbofloxacin ……..160 mg
Benzyl alcohol (E 1519)……15 mg

Clear yellow greenish to yellow brownish solution.

4. INDICATIONS

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. CONTRA-INDICATIONS

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

6. ADVERSE REACTIONS

In very rare cases, administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site which may persist up to 7 days after injection.
Fluoroquinolones are known to induce arthropathies. In cattle, such lesions were observed after a three days treatment with the 16% marbofloxacin solution. These lesions did not induce clinical signs and should be reversible, particularly if they were to be observed after a single administration.
In very rare cases, anaphylactic-type reactions with a potentially fatal outcome might occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
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 PERIOD

Meat and offal: 5 days
Milk : 48 hours

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.
Shelf-life after first opening the container: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
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.

12. SPECIAL WARNINGS

Special warnings for each target species
The efficacy of the product has not been tested on mastitis caused by Gram positive bacteria.

Special precautions for use in animals
Official and local antimicrobial policies should be taken into account when this 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 product should only be based on susceptibility testing.
Use of the product deviating from the instructions given in this 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.

User warnings
- People with known hypersensitivity to (fluoro)quinolones should avoid using this 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.

Use during pregnancy, lactation or lay
Studies in laboratory animals (rats, rabbits) did not show any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin. Safety of the product at 10 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
None known.

Overdose (symptoms, emergency procedures, antidotes), if necessary
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Approved: 11 September 2018