ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box: 20 ml, 50 ml, 60 ml,100 ml, 250 ml and 500 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor SOLO 100 mg/ml Solution for Injection for Cattle.
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active Substance:
Marbofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

20 ml / 50 ml / 60 ml / 100ml / 250 ml / 500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular Injection

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Meat and Offal: 3 days
Milk: 72 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

< EXP {day/month/year}>
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

FOR ANIMAL TREATMENT ONLY

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Ltd
Newry
Co. Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4332

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml, 250 ml and 500 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor SOLO 100 mg/ml Solution for Injection for Cattle.
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active Substance:
Marbofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml / 250 ml / 500 ml

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular Injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and Offal: 3 days
Milk: 72 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

< EXP {day/month/year}>
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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 SIGHTAND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Ltd
Station Works
Newry
County Down
Northern Ireland
BT35 6JP

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4332

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml, 50 ml, 60ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor SOLO 100 mg/ml Solution for Injection for Cattle.
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCES

100 mg/ml Marbofloxacin

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

20 ml, 50 ml, 60-ml

4. ROUTES OF ADMINISTRATION

Intramuscular Injection.

5. WITHDRAWAL PERIODS

Cattle: Meat and Offal: 3 days
Milk: 72 hours

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

< EXP {day/month/year}>
Shelf-life after first opening the immediate packaging: 28 days'
Once broached, use by _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Marbonor SOLO 100 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
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
Northern Ireland
BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor SOLO 100 mg/ml Solution for Injection for Cattle.
Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each ml contains:

Active Substance:
Marbofloxacin 100.0 mg

Excipients:
Monothioglycerol 1.0 mg
Metacresol 2.0 mg

A clear yellow to amber solution.

4. INDICATION(S)

Treatment of respiratory infections caused by susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Histophilus somni*.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.

In very rare cases (less than 1 animal in 10,000 animals), the administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which may persist for at least 12 days after injection. No other adverse effects were observed in cattle.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, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended dosage is 8 mg/kg bodyweight (2 ml / 25 kg bodyweight) administered in a single intramuscular injection. If the injection volume exceeds 20 ml it should be administered at two or more injection sites.

9. ADVICE ON CORRECT ADMINISTRATION

The vial may be broached up to 35 times. The user should choose the most appropriate vial size according to the bodyweight of the animal(s) to be treated.

10. WITHDRAWAL PERIOD

Meat and Offal: 3 days
Milk: 72 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
Do not store above 25^{o}C.
Protect from light.
Do not use after the expiry date stated on the label after “EXP”
Shelf-life after first opening the immediate packaging: 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.

12. SPECIAL WARNINGS

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 upon susceptibility testing. Use of the product deviating from the instructions given in the package insert may increase the prevalence of bacteria

resistant the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin. Safety of the product at 8 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
No sign of overdosage has been observed after administration of 3 times the recommended dose.
Signs such as neurological disorders may occur when the dose is exceeded. Do not exceed the recommended dose. Such signs should be treated symptomatically.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

People with known hypersensitivity to (fluoro)quinolones should avoid any contact with the veterinary medicinal product.
If the product comes into contact with the skin or eyes, rinse with copious amounts of water.
Do not drink, eat or smoke whilst using the veterinary medicinal product.
Wash hands after use.
Accidental self-injection can induce a slight irritation.
In case of accidental self-injection or ingestion, seek medical advice immediately and show package leaflet or the label to the physician.

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

The product is marketed in 20 ml, 50 ml, 100 ml, 250 ml and 500 ml amber type II glass vials and 60 ml, 100 ml, 250 ml and 500 ml amber co-ex plastic (polypropylene) vials.
Not all pack sizes may be marketed.

For animal treatment only.

Prescription Only Medicine

Approved: 30 January 2018

D. Austin