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 100 mg/ml Solution for Injection for cattle and pig
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 and Pigs (Sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Intramuscular, Subcutaneous or Intravenous Injection.
Pigs: Intramuscular Injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

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

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 SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4331

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 100 mg/ml Solution for Injection for cattle and pig
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active Substance;
Marbofloxacin 100.0mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml/ 250 ml / 500 ml

5. TARGET SPECIES

Cattle and Pigs (Sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Intramuscular, Subcutaneous or Intravenous Injection.
Pigs: Intramuscular Injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

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

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 SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4331

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 100 mg/ml Solution for Injection for cattle and pig
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

Cattle: Intramuscular, Subcutaneous or Intravenous Injection.
Pigs: Intramuscular Injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

6. BATCH NUMBER

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

7. EXPIRY DATE

EXP {day/month/year}Once broached, use by _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Marbonor 100 mg/ml Solution for Injection for cattle and pig

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

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works, Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor 100 mg/ml Solution for Injection for cattle and pig
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)

Cattle
Treatment of respiratory infections caused by susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis*.
Treatment of acute mastitis caused by *Escherichia coli* strains susceptible to marbofloxacin during the lactation period.

Sows
Treatment of Metritis Mastitis Agalactia Syndrome (postpartum dysgalactia syndrome, PDS) caused by bacterial strains susceptible to marbofloxacin.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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. However, in cattle the subcutaneous route was shown to be better tolerated locally than the intramuscular route.Therefore, the subcutaneous route is recommended in heavy cattle.

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

7. TARGET SPECIES

Cattle and Pigs (Sows)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible to avoid underdosing.

The recommended dosage is 2 mg marbofloxacin/kg bodyweight (1 ml of the product/50 kg bodyweight) in a single daily injection by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs. For the injections, the neck should be preferred in cattle and pigs

Treatment durations are 3 days in pigs and 3 to 5 days in cattle.

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 target species to be treated.

10. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25^{O}C.
Protect from light.
Shelf-life after first opening the immediate packaging: 28 days
Do not use after the expiry date stated on the label after "EXP"
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 susceptibilty testing. Use of the product deviating from the instructions given in the package insert may increase the prevelance of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by Gram-positive bacteria.

Overdose (symptoms, emergency procedures, antidotes):

No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively.
Signs such as neurological disorders may occur when the dose is exceeded. Such signs should be treated symptomatically.

Interaction with other medicinal products and other forms of interaction:

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

Pregnancy and lactation:

May be used in pregnant and lactating cows and sows.

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

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

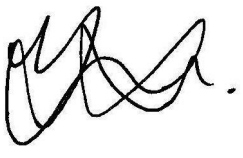
February 2023

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

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland



Approved: 22 February 2023