

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within: 28 days

Once broached use by.....

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

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

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBER

Vm 02000/4331

15. BATCH NUMBER

Lot {number}

7. SPECIAL STORAGE PRECAUTIONS

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8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS 20
ml, 50 ml, 60 ml Vial**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

100 mg/ml Marbofloxacin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within: 28 days.

Once broached use by.....

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active Substance:

Marbofloxacin 100.0 mg

Excipients:

Monothioglycerol 1.0 mg

Metacresol 2.0 mg

A clear yellow to amber solution.

3. Target species

Cattle and pigs (sows)

4. Indications for use

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 excipients.

6. Special warnings

Special warnings:

The efficacy data showed that the veterinary medicinal product has insufficient efficacy for the treatment of acute forms of mastitis induced by Gram-positive bacteria.

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when the 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. Whenever possible, fluoroquinolones should only be used based upon susceptibility testing. Use of the veterinary medicinal product deviating from the instructions given in the package insert may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

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 veterinary medicinal product comes into contact with skin or eyes, rinse with copious amounts of water.

Wash hands after use.

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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.

Overdose:

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.

7. Adverse events

Cattle and pigs (sows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site lesion ^{1, 2} , Injection site reactions ² (e.g. injection site pain and injection site swelling)
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¹ Inflammatory.

² Transient. May persist for at least 12 days after intramuscular injection.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: E-mail: adverse.events@vmd.gov.uk

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

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

Cattle: intramuscular, subcutaneous or intravenous use.

Pigs: intramuscular use.

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

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.

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 periods

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°C.

Protect from light.

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

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 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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 02000/4331

20 ml, 50 ml, 100 ml, 250 ml and 500 ml amber type II glass vials

60 ml, 100 ml, 250 ml and 500 ml amber co-ex plastic (polypropylene) vials.

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions :

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Prescription Only Medicine

Approved 31 July 2025
Gavin Hall