PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norotril Max 100 mg/ml Solution for Injection for Cattle
Enrofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Active Substance	
Enrofloxacin	100.0 mg
Excipients	
Benzyl alcohol (E1519)	20.0 mg
Butyl alcohol	30.0 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml
250 ml
500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIODS

Meat and offal: 14 days
Milk: 84 hours

9. SPECIAL WARNING(S), IF NECESSARY

Take care to avoid accidental self injection.
Read the package leaflet before use

10. EXPIRY DATE

EXP:
Shelf-life after first opening the container: 28 days.

Once broached, use by:…….

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.
Store in the original package in order to protect from light.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

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

For Animal Treatment Only.

POM-V 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

Norbrook Laboratories Limited

Station Works
Camlough Road
Newry
County Down
BT35 6JP
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4302

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norotril Max 100 mg/ml Solution for Injection for Cattle
)
Enrofloxacin

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active Substance	
Enrofloxacin	100.0 mg
Excipients	
Benzyl alcohol (E1519)	20.0 mg
Butyl alcohol	30.0 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml
250 ml
500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Meat and offal: 14 days
Milk: 84 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP:
Shelf-life after first opening the container: 28 days.

Once broached, use by…….

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.
Store in the original package in order to protect from light.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

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

For Animal Treatment Only.

POM-V 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

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
County Down
BT35 6JP
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4302

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

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

Marketing authorisation holder
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
County Down
BT35 6JP
Northern Ireland

Manufacturer responsible for batch release
Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited,
Station Works, Camlough Road,
Newry,
County Down,
Northern Ireland
BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norotril Max 100 mg/ml Solution for Injection for Cattle
Enrofloxacin

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

Each ml contains:

Active Substance	
Enrofloxacin	100.0 mg
Excipients	
Benzyl alcohol (E1519)	20.0 mg
Butyl alcohol	30.0 mg

A clear yellow solution

4. INDICATION(S)

Indicated for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma* spp. where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

5. CONTRAINDICATIONS

Do not use for prophylaxis.

Do not use in case of disturbances in growth of cartilage and/or during injury of locomotory system particularly on functionally loaded joints or due to body weight loaded joints.

Do not use in cases of resistance against other fluoroquinolones, due to the potential for cross-resistance.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.'

6. ADVERSE REACTIONS

Transient local reactions may occur at injection site.
Gastrointestinal disturbances may occasionally occur.

If you notice any serious effects or 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

Subcutaneous injection
To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
A single dose of 7.5 mg/kg bodyweight (7.5 ml per 100 kg bodyweight)
Not more than 15 ml should be administered at one subcutaneous injection site.

9. ADVICE ON CORRECT ADMINISTRATION

Not more than 15 ml should be administered at one subcutaneous injection site.

10. WITHDRAWAL PERIOD

Meat and offal: 14 days
Milk: 84 hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Do not freeze.
Store in the original package in order to protect from light.
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 vial and carton labels.
Do not use after the expiry date stated on the label after “EXP”.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Normal sterile precautions should be taken.
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 on susceptibility testing.
Use of the product deviating from the instructions given in the leaflet 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.
Laboratory studies have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects. The safety of enrofloxacin in pregnant and lactating animals has been shown in cattle. The product can be used during pregnancy and lactation.
Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines or phenols).
A dose of 25 mg/kg bodyweight administered for 15 consecutive days is tolerated without any clinical symptoms.
Clinical signs seen in significant overdosage include lethargy, lameness, ataxia, slight salivation and muscle tremors. In accidental overdose there is no antidote and treatment should be symptomatic.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

USER WARNINGS

The product is an alkaline solution.
Avoid contact of the skin and eyes with the product. Wear glasses and gloves when handling the product.

In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water. If irritation occurs, seek medical advice.
Take care to avoid accidental self injection: the product may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.
People with known hypersensitivity to the (fluoro)quinolones should avoid contact with the product.
Do not eat, drink or smoke when handling the product
Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, if any

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

June 2019

For Animal Treatment Only.

15. OTHER INFORMATION

POM-V	To be supplied only on veterinary prescription.

PACKAGE QUANTITIES:
1 x 100 ml, 4 x 100 ml and 12 x 100 ml
1 x 250 ml, 4 x 250 ml and 12 x 250 ml
1 x 500 ml, 4 x 500 ml and 12 x 500 ml

Not all pack size may be marketed.

Vm 02000/4302

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.

Approved 16 September 2019