PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC Xtra 600 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each single dose 5.4 g syringe contains:

Cloxacillin (as Benzathine salt) 600 mg in a long acting base.

Cloxacillin is a semi-synthetic penicillin derived from 6-aminopenicillanic acid.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

24 x 5.4 g syringes
120 x 5.4 g syringes

5. TARGET SPECIES

Dairy cows and heifers

6. INDICATION(S)

Noroclox DC Xtra is formulated for use in cows at the point of drying off, that is, immediately after the last milking of the lactation, in order to treat existing mastitis and to provide protection against further infections during the dry period.

Noroclox DC Xtra is a useful aid in reducing the incidence of summer mastitis in dry cows at risk.

Noroclox DC Xtra is active against Gram-positive organisms associated with mastitis. These include *Streptococcus agalactiae* and other *Streptococcus* species, penicillin-resistant and sensitive *Staphylococci* and *Arcanobacterium pyogenes*.

Noroclox DC Xtra is formulated with a long- acting base and maintains effective antibacterial levels in the majority of quarters in dry cows for at least 7 weeks and is non-irritant to udder tissue.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramammary infusion in dairy cows and heifers.

Dry Off Therapy: After the final milking of a lactation, milk out the udder completely, thoroughly clean and disinfect the teats and introduce the contents of one syringe into each quarter via the teat canal. Care should be taken to avoid contamination of the injector nozzle.

The syringe may only be used once. Part used syringes must be discarded.

8. WITHDRAWAL PERIOD

The product is not intended for use within 49 days of calving.

Meat and offal: 28 days

Milk: - 96 hours (4 days) after calving when dry period is more than 49 days.
- 53 days after treatment when dry period is 49 days or less.

Do not use the product in the treatment of lactating cows. Should this occur, milk should be discarded for 24 days, following which time milk should be tested until the levels of antibiotic are below the maximum acceptable residue level i.e., 0.03 μg/ml for cloxacillin.

In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period than stated above. In such cases milk should be withheld until levels of antibiotic are below the maximum acceptable residue level i.e., 0.03 μg/ml for cloxacillin.

9. SPECIAL WARNING(S), IF NECESSARY

The product is safe for use during pregnancy.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

When infusing heifers it is important that the syringe nozzle is not introduced into the teat. The recommended procedure is as follows:

The animal(s) should be properly restrained. The teats are cleaned and disinfected. The teat orifice is located and the nozzle of the syringe placed against it but NOT inserted. When the syringe plunger is depressed the antibiotic passes easily through the teat into the udder.

In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period. In such cases milk should be withheld until the levels of antibiotic are below the maximum acceptable residue level i.e. 0.03 mcg/ml for cloxacillin.

USER WARNINGS:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may

lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
Protective gloves should always be worn when infusing heifers, to avoid skin contact with the product.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
Wash hands after use.

10. EXPIRY DATE

EXP: DD/MM/YY

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

The syringe may only be used once. Part-used syringes must be discarded.

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

Dispose of waste material 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.

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
Co. Down
BT35 6JP
Northern Ireland

MANUFACTURED BY:
Norbrook Laboratories Limited
Newry
Co. Down
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

Vm 02000/4126

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

FURTHER INFORMATION:

Noroclox DC Xtra must not be used in the treatment of lactating cows.
Should this occur milk should be discarded for 24 days, following which time milk should be tested until the levels of antibiotic are below the maximum acceptable residue level i.e. 0.03 mcg/ml for cloxacillin.

LOGO

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufactured by:
Norbrook Laboratories Limited
Newry
Co. Down,
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC Xtra 600 mg Intramammary Suspension

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

Cloxacillin (as benzathine salt) 600 mg in a long acting base

4. PHARMACEUTICAL FORM

Intramammary Suspension
An oily off white suspension

5. PACKAGE SIZE

5.4g

6. INDICATION(S)

See carton text for indications, method and route of administration

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Dairy cows and heifers

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

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Do not use in lactating cattle. Not intended for use within 49 days of calving.
Meat and offal: 28 days
Milk: - 96 hours (4 days) after calving when dry period is more than 49 days.
- 53 days after treatment when dry period is 49 days or less

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
The syringe may only be used once. Part used syringes must be discarded

14. SPECIAL WARNING(S)

Protective gloves should be worn when infusing heifers.
Penicillins/cephalosporins may occasionally cause severe allergic reactions. See carton text for user warning and disposal advice.

15. EXPIRY DATE

EXP: DD/MM/YY

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. 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.

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

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER

Vm 02000/4126

21. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

22. OTHER INFORMATION

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

Approved: 27 July 2018