PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> 24 X/120 X SYRINGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC 500 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Noroclox DC (dry cow) is an off-white, stable intramammary suspension prepared under sterile conditions. Each single dose 4.5g syringe contains 500 mg cloxacillin [as cloxacillin benzathine] in a long acting base with 3% aluminium stearate. Benzathine cloxacillin is a semi synthetic penicillin derived from 6-amino penicillanic acid.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

Supplied in cartons of 24 and 120 syringes. Each single dose 4.5g syringe containing 500 mg cloxacillin (as cloxacillin benzathine).

5. TARGET SPECIES

Cattle, dairy cows.

6. INDICATION(S)

Noroclox DC is an intramammary suspension formulated for use in the dairy cow 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 is active against Gram-positive organisms associated with mastitis and is effective against *Streptococcus agalactiae, Streptococcus dysgalactiae* and other Streptococcal species, and *Arcanobacterium pyogenes.* As cloxacillin is not destroyed by staphylococcal penicillinase. Noroclox DC is active against penicillin resistant staphylococci which are an important cause of bovine mastitis. Noroclox DC maintains effective antibacterial levels in the dry cow udder for approximately four weeks, is bactericidal in action and is non-irritant in the udder tissue. Official national and regional antimicrobial policies should be taken into account when the product is used.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one syringe into each quarter via the teat canal.

8. WITHDRAWAL PERIOD

Meat and Offal: 28 days.

Not intended for use within 35 days of calving.
Milk for human consumption
may only be taken from 108 hours after calving. Should a cow calve earlier than 35 days after the last treatment, milk for human consumption may only be taken from 35 days plus 108 hours after the last treatment. Should a cow calve earlier than 35 days after treatment consult your veterinary surgeon. In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period than that stated above. In such cases, milk should be withheld until the levels of antibiotics are below the maximum accepted residue levels, i.e. 0.03 mcg/ml for cloxacillin.
The product must not be used in
the treatment of lactating cows.

9. SPECIAL WARNING(S), IF NECESSARY
OPERATOR WARNINGS

When infusing heifers, protective gloves should always be worn in order to avoid skin contact with the product.
Penicillins and cephalosporins may cause hypersensivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.
1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such presentations.
2. Handle this product with great care to avoid exposure taking all recommended precautions.
3. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store below 25°C. The syringe may only be used once. Part used syringes must be discarded. Keep Syringe in outer carton.

12. SPECIFIC 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 *[Distribution category]*

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

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

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4040

17. MANUFACTURER’S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE> 4.5 G SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC 500 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cloxacillin (as benzathine salt) 500mg
Ampicillin (as the trihydrate) 250mg

Long acting base with 3% aluminium stearate.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

4.5 g

5. TARGET SPECIES

Dairy cows.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

An intramammary suspension for use in dry cows only. Do not use in lactating cattle.
Not intended for use is

Do not use in lactating cattle.

Meat: 28 days
Milk: 156 Hours after calving.
Not intended for use within 49 days of calving.
If calving occurs before 49 days after the last treatment, milk for human consumption may only be taken after 49 days plus 156 hours after the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY
OPERATOR WARNINGS

Penicillins/cephalosporins may occasionally cause severe allergic reactions. See Carton Text for user warning.

Wash hands after use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

The syringe may only be used once.

Part used syringes must be discarded.
Keep syringe in outer carton.

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

See carton for disposal advice.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Newry
Co. Down, BT35 6 JP
Northern Ireland.

16. MARKETING AUTHORISATION NUMBER(S)
ManA 2000
Vm 02000/4046

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

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PACKAGE LEAFLET FOR:

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, Newry, Co. Down, BT35 6JP, Northern Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCLOX DC 500mg INTRAMAMMARY SUSPENSION

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

Noroclox DC (dry cow) is an off-white, stable intramammary suspension prepared under sterile conditions. Each single dose 4.5g syringe contains 500 mg cloxacillin [as cloxacillin benzathine] in a long acting base with 3% aluminium stearate. Benzathine cloxacillin is a semi synthetic penicillin derived from 6-amino penicillanic acid.

4. INDICATION(S)

Noroclox DC is an intramammary suspension formulated for use in the dairy cow 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 is active against Gram-positive organisms associated with mastitis and is effective against *Streptococcus agalactiae, Streptococcus dysgalactiae* and other Streptococcal species, and *Arcanobacterium pyogenes.* As cloxacillin is not destroyed by staphylococcal penicillinase. Noroclox DC is active against penicillin resistant staphylococci which are an important cause of bovine mastitis. Noroclox DC maintains effective antibacterial levels in the dry cow udder for approximately four weeks, is bactericidal in action and is non-irritant in the udder tissue. Official national and regional antimicrobial policies should be taken into account when the product is used.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Cattle, dairy cows

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

After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one syringe into each quarter via the teat canal.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and Offal: 28 days.
Not intended for use within 35 days of calving.
Milk for human consumption may only be taken from 108 hours after calving.
Should a cow calve earlier than 35 days after the last treatment, milk for human consumption may only be taken from 35 days plus 108 hours after the last treatment.
Should a cow calve earlier than 35 days after treatment consult your veterinary surgeon.
In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period than that stated above. In such cases, milk should be withheld until the levels of antibiotics are below the maximum accepted residue levels, i.e. 0.03 mcg/ml. for cloxacillin.
The product must not be used in the treatment of lactating cows.

11. SPECIAL STORAGE PRECAUTIONS

Store below 25°C. The syringe may only be used once. Part used syringes must be discarded. Keep syringe in outer carton.

12. SPECIAL WARNING(S)

OPERATOR WARNINGS

When infusing heifers, protective gloves should always be worn in order to avoid skin contact with the product. Penicillins and cephalosporins may cause hypersensivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.
1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such presentations.
2. Handle this product with great care to avoid exposure taking all recommended precautions.
3. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
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 LEAFLET WAS LAST APPROVED

October 2022

<Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

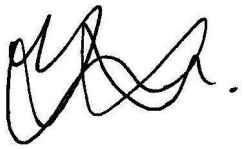
<15. OTHER INFORMATION>

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

ManA 2000
Vm 02000/4040

For Animal Treatment Only

Keep out of the reach and sight of children



Approved: 28 October 2022