PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> 24 X/120 X 4.5 G SYRINGE CARTON AND TUB LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Bovaclox DC is an off-white, stable intramammary suspension prepared under sterile conditions.

Each single dose 4.5 g syringe contains:
Cloxacillin (as benzathine salt) 500 mg
Ampicillin (as the trihydrate) 250 mg

in a long acting base with 3% aluminium stearate.
Ampicillin and cloxacillin are semi-synthetic penicillins derived from 6 aminopenicillanic acid.

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

4.5 g

Package Quantities:
Cartons of 24 and 120 syringes and buckets of 120 syringes, each syringe containing 500 mg cloxacillin as the benzathine salt and 250 mg ampicillin as the trihydrate.
Not all package sizes may be marketed.

5. TARGET SPECIES

Dairy Cattle

6. INDICATION(S)

Bovaclox DC (Dry Cow) is formulated for use in the dairy cow (including heifers) 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.

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

Bovaclox DC is active against both Gram-positive and Gram- negative organisms which are associated with mastitis and is effective against *Streptococcus agalactiae* and other *Streptococcus* species, penicillin resistant and sensitive staphylococci, *Corynebacterium* species, *Escherichia coli* and other susceptible Gram-negative bacteria.

Benzathine cloxacillin and ampicillin trihydrate in a long acting aluminium stearate base maintain effective antibacterial levels in the dry cow udder for approximately four weeks and are non-irritant to 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

Dry off therapy: 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

Do not use in cows with a short dry period.
Not intended for use within 49 days of calving.
Milk for human consumption may only be taken from 156 hours after calving.
Should a cow calve earlier than 49 days after the last treatment, milk for human consumption may only be taken from 49 days plus 156 hours after the last treatment.
Should a cow calve earlier than 49 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 and 0.004 mcg/ml ampicillin.
Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only 28 days from the last treatment.
The product must not be used in the treatment of lactating cows. Should this occur milk should be discarded for 30 days, following which time milk should be tested until antibiotic can no longer be detected.

9. SPECIAL WARNING(S), IF NECESSARY

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.

Operator warning- penicillin/cephalosporin sensitivity:

Protective gloves should always be worn when infusing heifers, to avoid skin contact with the product.

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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure, taking all recommended precautions.

3. 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.
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

Manufactured by:
Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

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

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

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

Bovaclox DC 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 Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

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

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

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Station Works
Newry
Co. Down, BT35 6JP
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Distributed by:
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16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4046

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

Bovaclox DC Intramammary Suspension

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

Bovaclox DC is an off-white, stable intramammary suspension prepared under sterile conditions. Each single dose 4.5 g syringe contains:

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

in a long acting base with 3% aluminium stearate. Ampicillin and cloxacillin are semisynthetic penicillins derived from 6-aminopenicillanic acid.

4. INDICATION(S)

Bovaclox DC (Dry Cow) is formulated for use in the dairy cow (including heifers) 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.
Bovaclox DC is a useful aid in reducing the incidence of summer mastitis in dry cows at risk. Bovaclox DC is active against both Grampositive and Gram-negative organisms which are associated with mastitis and is effective against *Streptococcus agalactiae* and other *Streptococcus* species, penicillin resistant and sensitive staphylococci, *Corynebacterium* species, *Escherichia coli* and other susceptible Gram-negative bacteria. Benzathine cloxacillin and ampicillin trihydrate in a long acting aluminium stearate base maintain effective antibacterial levels in the dry cow udder for approximately four weeks and are non-irritant to udder tissue. Official national and regional antimicrobial policies should be taken into account when the product is used.

5. CONTRAINDICATIONS

None

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

Dairy Cattle

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

Dry off therapy: 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

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.

10. WITHDRAWAL PERIOD(S)

Do not use in cows with a short dry period.
Not intended for use within 49 days of calving.
Milk for human consumption may only be taken from 156 hours after calving.
Should a cow calve earlier than 49 days after the last treatment, milk for human consumption may only be taken from 49 days plus 156 hours after the last treatment.
Should a cow calve earlier than 49 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 antibiotic are below the maximum accepted residue levels, i.e. 0.03 mcg/ml for cloxacillin and 0.004 mcg/ml ampicillin.
Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only 28 days from the last treatment.
The product must not be used in the treatment of lactating cows. Should this occur milk should be discarded for 30 days, following which time milk should be tested until antibiotic can no longer be detected.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. The syringe may only be used once. Part used syringes must be discarded. Keep syringe in outer carton. Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Operator warning - penicillin/cephalosporin sensitivity:
Protective gloves should always be worn when infusing heifers, to avoid skin contact with the product.
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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.

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

15. OTHER INFORMATION

PACKAGE QUANTITIES AVAILABLE:
Cartons of 24 and 120 syringes, each syringe containing 500 mg cloxacillin as the benzathine salt and 250 mg ampicillin as the trihydrate.

FURTHER INFORMATION

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

Marketing Authorisation Number:
Vm 02000/4046

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For Animal treatment Only.

Approved 28 October 2022