PARTICULARS TO APPEAR ON THE OUTER PACKAGE FOR 24 AND 120 SYRINGES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Xtra Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each single dose 5.4 g syringe contains:

Cloxacillin (as cloxacillin benzathine)	600 mg
Ampicillin (as ampicillin trihydrate.)	300 mg

in a long acting base.

Ampicillin and cloxacillin are semi-synthetic penicillins derived from 6-aminopenicillanic acid.

3. PHARMACEUTICAL FORM

Bovaclox DC Xtra is an off-white stable intramammary suspension, dry cow, prepared under sterile conditions

4. PACKAGE SIZE

5.4 g

Cartons of 24 and 120 syringes

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Bovaclox DC Xtra is 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.

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

Bovaclox DC Xtra 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.

Cloxacillin benzathine and ampicillin trihydrate in a long-acting base maintain effective antibacterial levels in the dry cow udder for up to 10 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. Avoid contamination of syringe nozzle.

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 maxium 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 WARNINGS:

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 reaction 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.

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 in 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 syringes may only be used once.

Part-used syringes must be discarded.

Keep container 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

For Animal Treatment Only.

POM-V

To be supplied only by 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

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 02000/4111

17. MANUFACTURER'S BATCH NUMBER

Bn.:

D.O.M.:

FURTHER INFORMATION:

Bovaclox DC Xtra must not be used in the treatment of lactating cows.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Xtra Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cloxacillin (as cloxacillin benzathine) 600 mg

Ampicillin (as ampicillin trihydrate.) 300 mg

In a long acting base.

3. PHARMACEUTICAL FORM

Intramammary suspension.

4. PACKAGE SIZE

5.4 g

5. TARGET SPECIES

Cattle

8. WITHDRAWAL PERIOD

Do not use in lactating cattle.

Not intended for use within 49 days of calving.

Milk withdrawal period: 49 days plus 156 hours.

Refer to carton text for details.

Cattle must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Protective gloves should be worn when infusing heifers.

Penicillins/Cephalosporins may occasionally cause severe allergic reactions

See carton for user warnings.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

The syringe must only be used once.

Part-used syringes must be discarded.

Keep container 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

For Animal Treatment Only.

POM-V

To be supplied only by veterinary prescription.

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Approved 28 October 2022