

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactaclox Intramammary Infusion

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Lactaclox is an off-white stable intramammary suspension prepared under sterile conditions.

Each single dose, 5 g syringe contains:

Ampicillin (as ampicillin sodium)75 mg
Cloxacillin (as cloxacillin sodium)200 mg

Cloxacillin sodium and ampicillin sodium are semi-synthetic penicillins derived from 6-aminopenicillanic acid.

3. PHARMACEUTICAL FORM

Intramammary infusion

4. PACKAGE SIZE

Cartons of 24 syringes

5. TARGET SPECIES

Cows

6. INDICATION(S)

Lactaclox is for the treatment of clinical mastitis in the lactating cow.

Lactaclox is effective against Gram-positive and Gram-negative bacteria including *Streptococcus agalactiae*, *Streptococcus dysgalactiae* and other streptococcal species; *Staphylococci* spp; *Arcanobacterium pyogenes*; *Escherichia coli* and other Gram-negative bacteria.

It can be safely administered to pregnant animals.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The contents of one syringe should be infused into each infected quarter via the teat canal immediately after milking, at 12 hour intervals for three consecutive milkings. Clean and disinfect the teat before each treatment. After infusion, massage the contents up into the udder, then dip the teat.

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption may only be taken from 60 hours (i.e. at the 5th milking) after the last treatment. Where any other routine is followed, consult your veterinary surgeon. With other milking routines, the basis of a veterinary surgeon's advice should be that milk may be taken for human consumption only after the same period from the last treatment. For example with three times a day milking with a product administered twice per day, milk for human consumption may only be taken at the 8th milking.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 4 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

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.

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

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 any unused product or 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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:

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: 02000/4044

17. MANUFACTURER’S BATCH NUMBER

B.N.:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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

Manufactured by:

Norbrook Laboratories Limited
Newry
Co. Down,
Northern Ireland

Distributed by:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactaclox Intramammary Infusion

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

Contents:

Cloxacillin (as cloxacillin sodium) 200 mg
Ampicillin (as ampicillin sodium) 75 mg

4. PHARMACEUTICAL FORM

Intramammary Infusion

5. PACKAGE SIZE

5g

6. INDICATION(S)

For intramammary use in lactating cattle.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

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

11. ADVICE ON CORRECT ADMINISTRATION

The contents of one syringe should be infused into each affected quarter via the teat canal immediately after milking, at 12 hour intervals for three consecutive milkings

12. WITHDRAWAL PERIOD

Milk may be taken from 60 hours after last treatment.
Meat withdrawal period - 4 days from last treatment.

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)

Penicillins/Cephalosporins may occasionally cause severe allergic reactions.

See carton text for user warnings, full dosage instructions 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 REACH AND SIGHT OF CHILDREN.

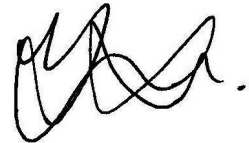
20. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4044

21. MANUFACTURER’S BATCH NUMBER

B.N.:
DOM:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 28 October 2022