SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactaclox Intramammary Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	Per 5g Syringe
Ampicillin (as ampicillin sodium)	75 mg
Cloxacillin (as cloxacillin sodium).	200 mg

Excipients

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary Infusion
An off-white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cows

4.2 Indications for use, specifying the target species

For the treatment of clinical bovine mastitis in the lactating cow caused by Gram-positive and Gram-negative bacteria including:

Streptococcus agalactiae
Streptococcus dysgalactiae
Other Streptococcal spp
Staphylococcus spp
Arcanobacterium pyogenes
Escherichia coli

4.3 Contraindications

None

4.4 Special Warnings for Each Target Species

Before infusion, the quarter should be milked out completely, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion, massage the product up into the udder, and then it is advisable to use a teat dip or spray.

4.5 Special Precautions for Use

i. Special Precautions for use **in animals**

There are no special precautions for use in animals.

ii. Special precautions to be taken by the person administering the product to the animals:

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 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.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

Lactaclox is specifically indicated for the treatment of clinical mastitis in lactating cows. It can be safely administered to pregnant animals.

4.8 Interactions with other medicinal products and other forms of interaction

None

4.9 Amount to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)

Not applicable

4.11 Withdrawal periods

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, Betalactam antibacterials, penicillins, for intramammary use, Combinations of penicillins and / or beta-lactamase inhibitors

ATCvet Code: QJ51CR50

5.1 Pharmacodynamic properties

Ampicillin possesses antibacterial activity against Gram-positive and Gram-negative bacteria. Cloxacillin is active against Penicillin G resistant staphylococci. Both beta-lactam antibiotics bind membrane bound proteins known as penicillin-binding proteins (PBP's).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Soft Paraffin
Liquid Paraffin

6.2 Incompatibilities

None Known

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

5g single dose white low density polyethylene syringe barrels and plunger, with white low density polyethylene cap.

Available in cartons of 24 single use syringes

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4044

9. DATE OF FIRST AUTHORISATION

10th December 1979

10. DATE OF REVISION OF THE TEXT

July 2010