SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5g syringe contains:

Active Substance:	**mg**
Cloxacillin (as Benzathine Cloxacillin)	500
Ampicillin (as Ampicillin Trihydrate)	250

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension
An off white suspension for intramammary infusion

4. CLINICAL PARTICULARS

4.1 Target species

Dairy Cattle

4.2 Indications for use, specifying the target species

For routine use in cows at drying off, to treat intramammary infections and to assist in preventing new infections occurring during the dry period.
It also aids in reducing the incidence of summer mastitis in dry cows and heifers at risk. Amongst the organisms found to be sensitive to Ampicillin and Cloxacillin are:

Streptococcus agalactiae
Streptococcus spp
Staphylococcus spp
Corynebacterium spp
Escherichia coli

4.3 Contraindications

None

4.4 Special Warnings for each target species

No special warnings.

4.4 Special precautions for use

i. Special precautions for use in animals

Official national and regional antimicrobial policies should be taken into account when the product is used.

When infusing heifers it is important that the syringe nozzle is not introduced into the teat. The animal should be properly restrained. The teat orifice is located and the nozzle of the syringe placed against it but NOT inserted.

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

Protective gloves shoould 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.

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 in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts to be administered and administration route

Dry off therapy: After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one tube into each quarter via the teat canal.

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

Not applicable.

4.11 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 antibitics 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.

5. PHARMACOLOGICAL PROPERTIES

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

ATC Vet Code: QJ51CR50

5.1 Pharmacodynamic properties

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Stearate
Paraffin, Liquid

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 25°C.
The syringe may only be used once. Part used syringes must be discarded.

6.5 Nature and composition of immediate packaging

4.5g white low density polyethylene syringe barrel and piston with a white low density polyethylene cap (snap-on) closure, supplied in cartons of 24 and 120 syringes and polypropylene buckets of 120 syringes.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm: 02000/4046

9. DATE OF FIRST AUTHORISATION

24th August 1981

10. DATE OF REVISION OF THE TEXT

July 2010