SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Xtra Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each 5.4g product contains:

Active Substance:	
Cloxacillin (as Cloxacillin benzathine)	600 mg
Ampicillin (as Ampicillin trihydrate)	300 mg

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension
An oily off white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

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

A useful aid in reducing the incidence of summer mastitis in heifers and dry cows at risk

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,

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Corynebacterium, Arcanobacteria 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.

4.3 Contraindications

None

4.4 Special Warnings for each target species

None known

4.5 Special precautions for use

i. Special precautions for use in animals

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.

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

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

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.

Sensitised individuals or those advised not to work with such preparations should not handle this product.

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This product should be handled with great care to avoid exposure, taking all recommended precautions.

Should symptoms develop following exposure such as skin rash, medical advice should be sought. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Safe for use during pregnancy

4.8 Interaction with other medicinal products and other forms of interaction

None known

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. Avoid contamination of the syringe nozzle.

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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.

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.

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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.

Must not be used in the treatment of lactating cows

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

Contains ampicillin and cloxacillin, which are both beta-lactam antibiotics. Their structures containing the same beta-lactam ring and thiazolidine ring common to all penicillins.

Beta-lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis only of growing cells. The difference in susceptibility between Gram-positive and Gram-negative bacteria depends on differences in receptor sites, on the relative amount of peptidoglycan present, on the ability of drugs to penetrate the outer cell membrane of Gram-negative bacteria and on resistance to the different types of beta-lactamase enzymes produced by the bacteria.

Ampicillin has a high activity against both Gram-positive and Gram-negative bacteria, but is inactivated by beta-lactamases.

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Cloxacillin is relatively resistant to staphylococcal beta-lactamases but is of lower activity than penicillin G against susceptible Gram-positive bacteria and is inactive against Gram-negative bacteria.

The combination of penicillinase-resistant penicillins, such as cloxacillin, with ampicillin, against common opportunist Gram-negative bacteria, has shown synergism in many cases.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.5 Nature and composition of immediate packaging

These intramammary syringes will be supplied in outer cartons of 24 and 120 syringes.
5.4g pre-filled intramammary syringes with high density polyethylene barrels and white or red plungers, closed with high density polyethylene snap on, red or white caps.
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 derived from such a veterinary medicinal products should be disposed of in accordance with local requirements.

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7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm: 02000/4111

9. DATE OF FIRST AUTHORISATION

11th April 1994

10. DATE OF REVISION OF THE TEXT

July 2010

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