SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC Xtra 600mg Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each 5.4 g syringe contains:
Cloxacillin 600 mg
(as benzathine salt)

For the 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

Dairy cows and heifers

4.2 Indications for use, specifying the target species

The product is formulated for use in cows 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.

The product is a useful aid in reducing the incidence of summer mastitis in dry cows at risk.

Cloxacillin is active against Gram-positive organisms which are associated with mastitis. These include *Streptococcus agalactiae* and other *Streptococcus* species, penicillin resistant and sensitive Staphylococci and *Arcanobacterium pyogenes*.

The product is formulated with a long-acting base and maintains effective antibacterial levels in the majority of quarters in dry cows for at least 7 weeks and is non-irritant to udder tissue.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

The product must not be used in lactating cows. Should this occur, milk should be discarded for 24 days, following which time milk should be tested until the levels of antibiotic are below the maximum acceptable residue limit i.e., 0.03 mcg/ml for cloxacillin.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

None known

ii) Special precautions to be taken by the person administering the veterinary medicinal product to 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.
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.
Protective gloves should always be worn when infusing heifers, to avoid skin contact with the product.
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.
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 is safe for use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amount(s) to be administered and administration route

For intramammary infusion in dairy cows and heifers

Dry Off Therapy: After the final milking of a lactation, milk out the udder completely, thoroughly clean and disinfect the teats and introduce the contents of one syringe into each quarter via the teat canal. Care should be taken to avoid contamination of the injector nozzle.

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

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

Not applicable.

4.11 Withdrawal period(s)

The product is not intended for use within 49 days of calving.

Meat and offal: 28 days

Milk: - 96 hours (4 days) after calving when dry period is more than 49 days.
- 53 days after treatment when dry period is 49 days or less.

Do not use this product in the treatment of lactating cows. Should this occur, milk should be discarded for 24 days, following which time milk should be tested until the levels of antibiotic are below the maximum acceptable residue level i.e., 0.03 μg/ml for cloxacillin

In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period than stated above. In such cases milk should be withheld until levels of antibiotic are below the maximum acceptable residue level i.e., 0.03 μg/ml for cloxacillin.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, Betalactam antibacterials, penicillins, for intramammary use, Betalactamase resistant penicillins

ATCvet Code: QJ51CF02

5.1 Pharmacodynamic properties

Cloxacillin is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins.

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

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Distearate
Liquid Paraffin

6.2 Major 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

5.4g white intramammary syringes with low density polyethylene barrel and white or orange plunger with white or orange low density polyethylene caps

Available in cartons of 24 and 120 unit-dose syringes

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 veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4126

9. DATE OF FIRST AUTHORISATION

10 March 1995

10. DATE OF REVISION OF THE TEXT

July 2018

Approved: 27 July 2018