Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC Xtra Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Cloxacillin Benzathine (1% lecithin coated) equivalent to cloxacillin 11.11% w/w

each 5.4 g syringe contains 600 mg cloxacillin

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cows and heifers.

4.2 Indications for use, specifying the target species

Noroclox DC Xtra 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.

Noroclox DC Xtra is a useful aid in reducing the incidence of summer mastitis in dry cows at risk.

Noroclox DC Xtra is active against Gram-positive organisms which are associated with mastitis. These include *Streptococcus agalactiae* and other *Streptococcus* species, penicillin resistant and sensitive Staphylococci, *Corynebacteriumpyogenes*.

Noroclox DC Xtra 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.

4.3 Contraindications

Do not use on cows which have a short dry period. Not intended for use within 42 days of calving.

Animals must not be slaughtered for human consumption during treatment.

Do not use in the treatment of lactating cows. Should this occur, milk should be discarded for 42 days, following which time milk should be tested until the levels of antibiotic are below the EU maximum residue limit of 30 µg/kg for cloxacillin.

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

Special precautions to be taken by the person administering the product to animals
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reaction 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.

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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Noroclox DC Xtra is safe for use during pregnancy.

Do not use in lactating cows.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For intramammary infusion in dairy cows and heifers.

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.

Summer Mastitis Therapy: In heifers, prior to the first calving and in adult cows, at risk to summer mastitis, clean and disinfect the teats and introduce the contents of one syringe into each quarter.

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)

Not for use in cows with dry periods of less than 42 days. If calving occurs before 42 days, milk must only be taken from 42 days plus 96 hours after the last treatment.

Milk for human consumption may only be taken 96 hours after calving in cows with dry periods greater than 42 days.

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Penicillins

ATC Vet Code: QJ51CFO2

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

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and composition of immediate packaging

Noroclox DC Xtra will be supplied in cartons of 24 and 120 syringes. Each 5.4g syringe containing 600mg Cloxacillin.
Not all pack sizes may be marketed.

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

Unused product and containers should be disposed of in accordance with guidance from an appropriate waste regulation authority.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first autorisation: 15 May 1996
Date of last renewal: 15 May 2006

10 DATE OF REVISION OF THE TEXT

January 2019