Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:
Active Substance
Cloxacillin (as Benzathine Salt) 500 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary Suspension. An off-white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows

4.2 Indications for use, specifying the target species

For routine use in cows at drying-off to treat existing intramammary infections and to assist in preventing new infections occurring during the dry period.
It is effective against:

Streptococcus agalactiae
Streptococcus dysgalactiae
Other Streptococcal spp.
Staphylococci spp
Corynebacterium pyogenes

Noroclox DC maintains effective antibacterial levels in the dry cow udder for approximately 4 weeks and is bactericidal in action.

4.3 Contraindications

Do not use in lactating animals. 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 30mcg/kg for cloxacillin.

Do not use in cows with a dry period of less than 4 weeks.

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

4.4 Special warnings for each target species

In the event of accidental treatment of lactating cows, the milk should be discarded for 42 days following which time the milk should be tested until antibiotics can no longer be detected.

4.5 Special precautions for use

Special precaution(s) for use in animals

Before infusion, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injection nozzle. Following infusion, it is advisable to use a teat dip or spray.

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

Penicillins and cephalosporins may cause hypersensitivity 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 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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Noroclox DC can be safely administered during pregnancy however this product is contraindicated for use in lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

The contents of one intramammary syringe should be infused into each quarter immediately after the final milking of a lactation.

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

Not applicable.

4.11 Withdrawal period(s)

Milk for human consumption may only be taken after 96 hours post calving with a dry period of more than 28 days, or 28 days plus 96 hours after the last infusion in cows with a dry period of 28 days or less.
Animals may not be slaughtered for human consumption until 28 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, Beta-lactam antibacterials
ATCvet Code: QJ51CF02

5.1 Pharmacodynamic properties

Cloxacillin is active against penicillin G resistant staphylococci. It binds to membrane bound proteins known as PBP's (Penicillin-binding proteins) that are located beneath the cell wall.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate

Liquid paraffin

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and composition of immediate packaging

A sterile 4.5 g single dose polyethylene white syringe with an orange or white plunger and an orange or white end cap, presented in cartons of 24 and 120 syringes and buckets of 120 syringes.

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

Any unused product or waste material should be disposed of in accordance with any guidance from an appropriate waste regulation authority.
Empty packs should be incinerated

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1987
Date of last renewal: 30 September 2007

10 DATE OF REVISION OF THE TEXT

January 2019