## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox DC Intramammary Suspension

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5 g syringe contains:

**Active substance:**

Cloxacillin (as Benzathine Salt) 500 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Aluminium stearate |
| Liquid paraffin |

Intramammary Suspension. An off-white suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cows.

### 3.2 Indications for use for each 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*

The veterinary medicinal product maintains effective antibacterial levels in the dry cow udder for approximately 4 weeks and is bactericidal in action.

### 3.3 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 30 µg/kg for cloxacillin.

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

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

### 3.4 Special warnings

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.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

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. People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the veterinary medicinal product.

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 immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty breathing, are more serious symptoms and require urgent medical attention.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy:

The veterinary medicinal product can be safely administered during pregnancy.

Lactation:

The veterinary medicinal product is contraindicated for use in lactating animals.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

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

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

### 3.12 Withdrawal periods

Meat and offal: 28 days.
Milk: 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.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QJ51CF02

### 4.2 Pharmacodynamics

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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Not applicable.

### 5.2 Shelf life

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

### 5.3 Special precautions for storage

Store below 25 °C.

### 5.4 Nature and composition of immediate packaging

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.

Outer packaging and sales presentations:

- Cartons of 24 syringes and 120 syringes
- Buckets of 120 syringes.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/011/001

## 8. DATE OF FIRST AUTHORISATION

01/10/1987

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

29/05/2024

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).