IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10999/002/001**
Case No: 7003617

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Norbrook Laboratories Limited

Station Works, **Newry**, **Co. Down BT35 6JP**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Noroclox QR

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroclox QR

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose 5 g syringe contains:

Active Substance

Cloxacillin (as Sodium Salt) 200 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows

4.2 Indications for use, specifying the target species

For the treatment of clinical mastitis in lactating cows caused by the following Gram-positive organisms:

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

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

Special Precautions to be taken by the Person Administering the Product to Animals

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

1. Do not handle this 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 a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

Noroclox QR is specifically indicated for the treatment of clinical mastitis in the lactating cow. It can be safely administered to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

The contents of one syringe should be infused into the affected quarter via the teat canal, immediately after milking, at 12 hour intervals for three consecutive milkings. Clean and disinfect the teat before each treatment.

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

Not applicable.

4.11 Withdrawal Period(s)

Milk for human consumption must not be taken from a cow during treatment.
Milk for human consumption may only be taken from 60 hours after the final treatment.
Animals must not be slaughtered for human consumption during treatment.
Cattle for human consumption may be slaughtered only after 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use; Beta-lactamase resistant penicillins; Cloxacillin

ATCvet code: QJ51CF02

5.1 Pharmacodynamic properties

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soft White Paraffin
Liquid Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
For single use only, unused product should be discarded after treatment.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A sterile off-white suspension packaged in 5g single-dose white syringes with low density polyethylene barrel, plunger and end cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Ltd.,
Station Works,
Newry,
Co. Down, BT35 6JP,
Northern Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT