Norbrook Laboratories Ltd

Telephone:01536 741147

Website:www.norbrook.com

Email:gbenquiries@norbrook.co.uk

Noroclox DC 500 mg Intramammary Suspension

Species: Cattle

Therapeutic indication:Pharmaceuticals: Antimicrobials: Intramammaries: Dry cow

Active ingredient: Cloxacillin Benzathine

Product: Noroclox DC 500 mg Intramammary Suspension

Product index: Noroclox DC

Cattle - milk:108 hours

Cattle - meat:28 days

Withdrawal notes: See datasheet

Incorporating:

Qualitative and quantitative composition

Each 4.5g syringe contains:

Active substance(s):

Cloxacillin (as Cloxacillin benzathine)

Excipients:

For a full list of excipients, see section Pharmaceutical Particulars

Pharmaceutical form

Intramammary Suspension.

An off-white Intramammary Suspension.

Clinical particulars

Target species

Cattle, dairy cows

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

•Arcanobacterium pyogenes

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

Contraindications

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

Special Warnings for each target species

None.

Special precautions for use

Special precautions for use in animals

Official national and regional antimicrobial policies should be taken into account when the product is used.

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 veterinary medicinal product to animals

When infusing heifers, protective gloves should always be worn in order to avoid skin contact with the product.

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.

•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.

Adverse reactions (frequency and seriousness)

None known.

Use during pregnancy, lactation or lay

Can be safely administered during pregnancy.

Interaction with other medicinal products and other forms of interaction

None known.

Amounts to be administered and administration route

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

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

Not applicable.

Withdrawal period

Meat and Offal: 28 days

Not intended for use within 35 days of calving.

Milk for human consumption may only be taken from 108 hours after calving. Should a cow calve earlier than 35 days after the last treatment, milk for human consumption may only be taken from 35 days plus 108 hours after the last treatment.

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

The product must not be used in the treatment of lactating cows.

Pharmacological particulars

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ51CF02

Pharmacodynamic properties

Cloxacillin is a member of the Beta-lactam group and 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, thereby disrupting cell walls synthesis. Cloxacillin is bactericidal.

Pharmaceutical particulars

List of excipients

•Aluminium Stearate

•Liquid Paraffin

Incompatibilities

None known

Shelf life

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

Special precautions for storage

Do not store above 25°C.

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

Nature and composition of immediate packaging

4.5 g white pre-filled Intramammary syringes with low density polyethylene barrels and white or orange plungers closed with low density polyethylene white or orange end caps.

Available in cartons of 24 or 120 syringes, or buckets of 120 syringes.

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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

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

Marketing Authorisation Number

Vm 02000/4040

Significant changes

Date of the first authorisation or date of renewal

NOAH Compendium

21 November 1979

Date of revision of the text

August 2011

Any other information

Nil.

Legal category

Legal category:POM-V

GTIN

GTIN description: Noroclox DC (4.5g)

GTIN:5023534003878

GTIN description: Noroclox DC 4.5g

GTIN:5023534003885