NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Xtra

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose 5.4g syringe contains:

Active substances:
600 mg Cloxacillin (as benzathine salt) and 300mg Ampicillin (as the trihydrate).

Excipients:

Qualitative composition of excipients and other constituents
Aluminium Stearate
Liquid Paraffin

An oily, off-white suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is formulated for use in the dairy cow 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.

The veterinary medicinal product is a useful aid in reducing the incidence of summer mastitis in heifers and dry cows at risk.

The veterinary medicinal product is active against both Gram-positive and Gram-negative organisms, which are associated with mastitis and is effective against *Streptococcus agalactiae* and other Streptococcus species, Penicillin resistant and sensitive Staphylococci, Corynebacterium species, *Escherichia coli* and other susceptible Gram- negative bacteria.

Cloxacillin benzathine and ampicillin trihydrate in a long-acting base maintain effective antibacterial levels in the dry cow udder for up to 10 weeks and are non-irritant to udder tissue.

3.3 Contraindications

Do not use on cows which have a short dry period.

Not intended for use within 49 days of calving.
(Refer to 3.12 for withdrawal periods)

In cows suffering from hypocalcaemia, it may be necessary to withhold milk for a longer period until the levels of antibiotic are below the EU maximum residue limit.

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product to animals:

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.

People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the veterinary medicinal product. This product should be handled with great care to avoid exposure, taking all recommended precautions.

Should symptoms develop following exposure such as skin rash, medical advice should be sought. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product in order to avoid skin contact with the product.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions (frequency and seriousness)

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 and lactation:
The veterinary medicinal product is safe for use during pregnancy.
The veterinary medicinal product must not be used in the treatment of lactating cows.

3.8 Interaction with other medicinal products and other forms of interactions

None known.

3.9 Administration routes and dosage

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 syringe into each quarter via the teat canal.

Summer Mastitis Therapy: Prior to the first calving, whilst at risk of summer mastitis, clean and disinfect the teats and introduce the contents of one syringe into each quarter.

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

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 period(s)

Meat and offal: 28 days.
Milk: 156 hours.

Do not use on cows which have a short dry period. Not intended for use within 49 days of calving.

Should a cow calve earlier than 49 days after the last treatment, milk for human consumption may only be taken from 49 days plus 156 hours after the last treatment.

4. PHARMACOLOGICALINFORMATION

4.1 ATCvet Code: QJ51CR50

4.2 Pharmacodynamics

The veterinary medicinal product contains ampicillin and cloxacillin which are both beta-lactam antibiotics. Their structures containing the same beta-lactam ring and thiazolidine ring common to all penicillins.

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. The difference in susceptibility between Gram-positive and Gram-negative bacteria depends on differences in receptor sites, on the relative amount of peptidoglycan present, on the ability of drugs to penetrate the outer cell membrane of Gram-negative bacteria and on resistance to the different types of beta-lactamase enzymes produced by the bacteria.

Ampicillin has a high activity against both Gram-positive and Gram-negative bacteria, but is inactivated by beta-lactamases.

Cloxacillin is relatively resistant to staphylococcal beta-lactamases but is of lower activity than penicillin G against susceptible Gram-positive bacteria and is inactive against Gram-negative bacteria.

The combination of penicillinase-resistant penicillins, such as cloxacillin, with ampicillin, against common opportunist Gram-negative bacteria, has shown synergism in many cases.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Store below 25 °C.

5.4 Nature and composition of immediate packaging

Immediate packaging: High density polyethylene syringes with high density polyethylene caps containing 5.4 g of suspension.

Outer packaging and sales presentations:

- Cartons of 24 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. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7.MARKETING AUTHORISATION NUMBER(S)

VPA22664/038/001

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/06/1993

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

19/02/2024

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).