1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5 g syringe contains:

Active substances:

500 mg Cloxacillin (as Cloxacillin Benzathine) and 250 mg Ampicillin (as Ampicillin Trihydrate)

Excipients:

Qualitative composition of excipients and other constituents
Aluminium stearate
Liquid paraffin

An off-white suspension.

3. CLINICAL PARTICULARS

3.1 Target Species

Dairy cattle.

3.2 Indications for use for each target species

For routine 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. It also aids in reducing the incidence of summer mastitis in dry cows at risk. The veterinary medicinal product is active against:

Streptococcus spp.
Staphylococcus spp.
Corynebacterium spp.

3.3 Contraindications

Do not use in lactating cows.

Do not use within 45 days of calving.

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

3.4 Special warnings for each target species

In the event of accidental treatment of lactating cows, the milk should be discarded for 30 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 use in the target species:

When infusing cows it is important that the syringe nozzle is not introduced into the teat. The animal 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 orifice into the udder.

Special precautions to be taken by the person administering the veterinary medicinal 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. 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 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.

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 and lactation:
The product must not be used in the treatment of lactating cows. In freshly calved cows which develop hypocalcaemia, milk should be tested for freedom from antibiotics before being used for human consumption.

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Dry off therapy: After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one tube into each quarter via the teat canal.

Summer Mastitis Therapy: Prior to the first calving, whilst at risk to summer mastitis, clean and disinfect the teats and introduce the contents of one syringe into each quarter at 3 week intervals. During

the summer mastitis period, all dry cows should receive a repeated infusion of one syringe into each quarter at 3 week intervals throughout their dry period in addition to the routine drying off therapy.

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: 120 hours.

Do not use in cows with a short dry period. Not intended for use within 45 days of calving. Should a cow calve earlier than 45 days after the last treatment, milk for human consumption may only be taken from 45 days plus 120 hours after the last treatment.

Animals must not be slaughtered for human consumption during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code: QJ51RC

4.2 Pharmacodynamics

Cloxacillin is active against Penicillin G resistant staphylococci. Ampicillin possesses antibacterial activity against Gram-positive and Gram-negative bacteria. Both antibiotics bind to membrane bound proteins known as penicillin binding proteins (PBP's).

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not applicable.

5.2 Shelf-life

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

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

4.5 g single dose white polyethylene, self-venting click-lock syringes.
Supplied in cartons of 24 and 120 syringes and polypropylene 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 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)

VPA22664/005/001

8. DATE OF FIRST AUTHORISATION

01/10/1987

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

12/04/2024

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).