

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovaclox DC Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5g syringe contains:

Active Substance: **mg**

Cloxacillin (as Benzathine salt) 500

Ampicillin (as Trihydrate) 250

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension

An off white suspension for intramammary infusion

4. CLINICAL PARTICULARS

4.1 Target species

Cows at drying off period

4.2 Indications for use, specifying the target species

For routine use in cows at drying off, to treat intramammary infections and to assist in preventing new infections occurring during the dry period.

It also aids in reducing the incidence of summer mastitis in dry cows and heifers at risk. Amongst the organisms found to be sensitive to Ampicillin and Cloxacillin are:

Streptococcus agalactiae

Streptococcus spp

Staphylococcus spp

Corynebacterium spp

Escherichia coli

4.3 Contraindications

Do not use in lactating cows.

Do not use in cows with a short dry period.

Do not use within 45 days of calving.

4.4 Special Warnings for each target species

No special warnings.

4.4 Special precautions for use

i. Special precautions for use in animals

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

When infusing heifers it is important that the syringe nozzle is not introduced into the teat. The animal should be properly restrained. The teat orifice is located and the nozzle of the syringe placed against it but NOT inserted.

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

Protective gloves should always be worn when infusing heifers, 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 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 or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to

the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>

4.7 Use during pregnancy, lactation or lay

The product 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

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.

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

Not applicable.

4.11 Withdrawal period

Milk: 120 hours after calving.

Should a cow calve earlier than 45 days after the last treatment, milk may be taken from 45 days + 120 hours after the last treatment.

Should a treatment of lactating cows occur, milk should be discarded for 30 days, following which time milk should be tested until antibiotic can no longer be detected.

In cows suffering from hypocalcaemia, milk should be tested until it is clear of antibiotic before it can be used for human consumption.

Meat: 28 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for intramammary use, Beta-lactam antibacterials, penicillins, for intramammary use, Combinations of penicillins and / or beta-lactamase inhibitors.

ATC Vet Code: QJ51CR50

5.1 Pharmacodynamic properties

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)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Stearate
Liquid Paraffin

6.2 Incompatibilities

None known

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.
The syringe may only be used once. Part used syringes must be discarded.

6.5 Nature and composition of immediate packaging

4.5g white low density polyethylene syringe with a white low density polyethylene cap, supplied in a carton box of 24 syringes.

6.6 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 products should be disposed of in accordance with local requirements.

7. MANUFACTURER

Norbrook Laboratories Limited
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Newry
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BT35 6JP
Northern Ireland
United Kingdom

8. MARKETING AUTHORISATION HOLDER

Abic Veterinary Products Ltd.
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9. MARKETING AUTHORISATION NUMBER

083-60-92376-00

Revised in August 2025 according to MoH's guidelines.