Veterinary Medicine User Leaflet

Veterinarian Prescription only medicine

For animal use only

1. **NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE:**
   Bovaclox DC Veterinary, Intramammary Suspension

2. **ACTIVE INGREDIENTS:**
   Each 4.5 g syringe contains:

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

   For a full list of excipients, see section 13 “further information”.

3. **Indications for use:**
   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 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.
   Therapeutic Group: Antibacterials of the penicillins and Beta-lactams families.

4. **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.

5. **Adverse reactions:**
   No known undesirable effects.

   Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link: https://sideeffects.health.gov.il

6. **Target Species:**
   Cows at drying off period

7. **Amounts to be administered and administration route:**
   Dry off therapy: Introduce the contents of one syringe into each udder quarter.

8. **How to use the product:**
   After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one syringe into each udder quarter via the teat canal.

9. **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.

10. **Warnings:**

- Special precautions regarding the use of the medicine for the target animal:

No special precautions.

- Special safety precautions regarding the use of the medicine in animals:
  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. When the syringe plunger is depressed the antibiotic passes easily into the udder.
- 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 reactions 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.
- Use during pregnancy and lactation:
  The product can be safely administered to pregnant animals.
- Interactions with other medicinal products and other forms of interactions:
  None.
- Overdose:
  Not applicable.
- Incompatibilities:
  None known.

11. Storage instructions:

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants and thereby prevent poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C.
- The syringe may only be used once. Part used syringes must be discarded.

12. 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 as toxic waste. Do not dispose in sewage.

13. FURTHER INFORMATION:

- **In addition to the active ingredients the product also contains:**
  Aluminium Stearate, Liquid Paraffin
- **Pharmaceutical form:**
  An off-white suspension.
- **Packaging sizes:**
  A white LDPE syringe containing 4.5 g suspension, closed with an LDPE cap and packed in a carton box containing 24 syringes.
- **Registration holder:**
  Abic Veterinary Products Ltd., 2 Hanegev Street, Airport City, 7019900
- **Manufacturer:**
  Norbrook Laboratories Limited., Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, Northern Ireland, UK

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- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 083-60-92376-00