The format of this leaflet was determined by the Ministry of Health and its contents was checked and approved by it

For veterinary use only

Requires a veterinarian's prescription

1. Cobactan LC Veterinary

Ointment for intramammary use

2. COMPOSITION:

Each 8 gram syringe contains:

Cefquinome (as Sulfate) 75 mg

A list of inactive ingredients is detailed in the "Further Information" section.

3. WHAT IS THE MEDICINE INTENDED FOR:

An intramammary ointment for the treatment of mastitis in lactating cows caused by: *Staphylococcus Aureus, Streptococcus uberis, Streptococcus dysgalactiae, Escherichia coli,* and other cefquinome-sensitive bacteria.

Therapeutic group: Antibiotics of the cephalosporin group

4. CONTRAINDICATIONS:

Not to be administered to animals known to be hypersensitive to cephalosporin antibiotics or other ß-lactam antibiotics.
Do not use a cleaning towel if a lesion/sore is present on the teat.

5. SIDE EFFECTS:

In very rare cases, anaphylactic reactions have been reported in animals after administration of Cobactan LC.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. TARGET ANIMALS:

Lactating cows

7. METHOD OF ADMINISTRATION AND DOSAGE:

For intramammary administration every 12 hours after milking, for three consecutive milkings.

8. ADMINISTRATION OF MEDICINAL PRODUCT:

Gently milk out the contents of the affected quarter. Thoroughly clean the teat area and canal orifice with a cleaning towel, gently infuse the contents of the syringe into the udder canal of the affected quarter. Gently massage the teat and udder area in order to disperse the product throughout the entire affected area. Repeat the treatment every 12 hours after milking, for three consecutive milkings.

9. **WITHDRAWAL PERIOD:**

Meat – do not slaughter cows for human consumption during treatment and for 48 hours following the last treatment. Do not use the milk for human consumption during and following treatment and for 96 hours following the last treatment.

10**. PRECAUTIONS:**

- Special precautions regarding use in the target animal
  Whenever possible, use of Cobactan LC should be based on susceptibility testing. Local regulations (if they exist) should be taken into account when administering antimicrobial medicines to farm animals.

  Inappropriate use may increase the prevalence of resistant to cefquinomes and may decrease the effectiveness of treatment with cephalosporins, due to the potential for cross-resistance.

- Special safety precautions to be taken by the person handling the product
  Penicillins or cephalosporins may cause allergic reactions following injection, inhalation, swallowing or skin contact. Hypersensitivity to penicillins may also lead to cephalosporins sensitivity and vice versa. These allergic reactions may be serious. Therefore, take the following precautionary measures:
  - Do not handle the product if you know you are sensitive to these substances, or if you have been told not to work with such preparations.
  - Handle the product with care, taking all precautionary measures to avoid exposure.
  - If you develop signs of hypersensitivity, such as skin inflammation, refer to the doctor and show him these precautions. Swelling of the face, lips or eyes are more serious signs of such sensitivity and require urgent medical attention.
  - Do not reuse the syringe. A partly used syringe must be discarded.
  - Wash hands after using cleaning towels and wear gloves if sensitivity to isopropyl alcohol is known or suspected.

- Pregnancy and lactation
  Cobactan LC is intended for use during lactation.

- Interactions with other medicines and other forms of interactions
  It is known that a cross-sensitivity to cephalosporins exists in bacteria sensitive to the cephalosporin group.

- Overdose
  No symptoms have been observed following an overdose.

11. **STORAGE INSTRUCTIONS:**

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid 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.
- Dispose of the used syringe in a safe manner.

12. **INSTRUCTIONS FOR THE DISPOSAL OF THE PRODUCT/UNUSED PRODUCT AFTER USE:**

Do not discard any remaining medicine into the wastewater or waste bin. Ask the veterinarian how to dispose of any medicinal waste in order to protect the environment.

13. **FURTHER INFORMATION:**

- In addition to the active ingredient, the medicine also contains:
  White soft paraffin, Liquid paraffin
- What does the medicine look like and what are the contents of the package:
  White to slightly yellow, oily, viscous and homogeneous ointment.
- The package contains 15 syringes, each containing 8 gram of ointment, and 15 cleaning towels.
- **License holder name and address:** Intervet Israel Ltd., Neve-Ne'eman Industrial Zone, Hod HaSharon 45240.
- **Manufacturer name and address:** Intervet International GmbH,

  Feldstrasse 1 A, 85716 Unterschleissheim, Germany

This leaflet was checked and approved by the Ministry of Health on 18.04.2017

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 082-72-92316-00

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