PATIENT PACKAGE INSERT FOR A VETERINARY PRODUCT

The medicine is only dispensed according to veterinarian's prescription
For veterinary use only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT, DOSAGE FORM AND CONCENTRATION

Cobactan 2.5% Veterinary
Suspension for Intramuscular (I.M) Injection

2. ACTIVE INGREDIENTS:

Each 1 ml contains:
Active ingredient:
Cefquinome (as sulfate) 25mg (equivalent to cefquinome sulfate 29.4 mg)

A list of inactive ingredients is detailed in section 13 "Further Information".

3. WHAT IS THE MEDICINE INTENDED FOR:

For the treatment of bacterial infections in cattle and pigs caused by gram positive and gram negative microorganisms sensitive to cefquinome.

Therapeutic group: Fourth generation cephalosporins.

Cattle:

1. Respiratory diseases caused by *Pasteurella multocida* and *Mannheimia haemolytica*.
2. Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot).
3. Acute *E.coli* mastitis with signs of systemic involvement.
4. *E.coli* septicaemia in calves.

Pigs:

1. For the treatment of bacterial infections of the lungs and respiratory tract caused by *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae, Streptococcus suis* and other cefquinome-sensitive organisms.
2. Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E. coli, Staphylococcus spp.* and other cefquinome-sensitive organisms.

Piglets:

1. Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
2. For the treatment of arthritis caused by *E. coli, Streptococcus spp.,* and other cefquinome-sensitive organisms.
3. Epidermitis (mild to moderate lesions) caused by *Staphylococcus hyicus.*

4. CONTRAINDICATIONS:

- Do not use in animals, which are known to be hypersensitive to ß-lactam
- Antibiotics.Cross-sensitivity to cephalosporins is known to exist in bacteria sensitive to the cephalosporin group.
- Do not inject into animals weighing less than 1.25 kg body weight.
- Do not use in poultry (including eggs) due the risk of spread of antimicrobial resistance to antibiotics in humans.

5. SIDE EFFECTS:

Use of the veterinary medicinal productmay result in a localized tissue reaction. Tissue lesionsare repaired15 days after the last injection administration of the veterinary medicinal product..
Hypersensitivity reactions to cephalosporins are rare.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform the veterinary surgeon.

Reporting side effects:
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://sideeffects.health.gov.il/

6. TARGET ANIMALS:

Cattle and pigs.

7. METHOD OF ADMINISTRATION AND DOSAGE FOR EACH TARGET ANIMAL AND/OR INDICATION:

All treatments are administered by intramuscular (I.M) injection

Species	Indication	Dosage	Frequency
Cattle	Respiratory diseases caused by *Pasteurella multocida* and *Mannheimia haemolytica*	1 mg cefquinome/kg body weight (equivalent to 2 ml/50 kg body weight)	Once daily for 3- 5 consecutive days
	Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg body weight (equivalent to 2 ml/50 kg body weight)	Once daily for 3-5 consecutive days
	Acute *E. coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg body weight (equivalent to 2 ml/50 kg body weight)	Once daily for 2 consecutive days
Calves	*E. coli* septicaemia	2 mg cefquinome/kg body weight (equivalent to 4 ml/50 kg body weight)	Once daily for 3-5 consecutive days
Pigs	Respiratory diseases	2 mg cefquinome/kg body weight (equivalent to 2 ml/25 kg body weight)	Once daily for 3 consecutive days
	MMA	2 mg cefquinome/kg body weight (equivalent to 2 ml/25 kg body weight)	Once daily for 2 consecutive days
Piglets	Meningitis, arthritis, epidermitis	2 mg cefquinome/kg body weight (equivalent to 2 ml/25 kg body weight)	Once daily for 5 consecutive days

8. ADMINISTRATION OF MEDICINAL PRODUCT:

Studies have indicated the advisability of giving second and subsequent injections, each one, at a different injection site. The preferred injection site is in muscular tissue in the mid neck.
Shake the vial well before use.
To ensure the correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
The product does not contain an antimicrobial preservative.
Swab the vial septum before removing each injection dose.
Use a dry sterile needle and syringe.
Use an appropriately graduated syringe that allows accurate administration of the required

dose volume. This is particularly important when injecting small volumes, for example, when treating piglets.
The cap may be safely punctured up to 25 times.
When treating groups of animals, automatic injection equipment should be used.

9. WITHDRAWAL PERIOD:

Withdrawal period for slaughtering:
Cattle - 5 days after termination of treatment.
Pigs - 3 days after termination of treatment.
Withdrawal period for milk:
Cows – One day after termination of treatment.

10. PRECAUTIONS:

Special precautions regarding the safety of use of the medicine in animals

Cobactan 2.5% Veterinary is intended for treatment of specific animals. Do not use Cobactan 2.5% Veterinary for disease prevention or as a part of herd health programme. The treatment of groups of animals should be strictly restricted to ongoing disease outbreaks, according to the approved conditions for use.

Special safety precautions to be taken by the person handling the product

Care should be taken to avoid accidental self-injection.
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this veterinary medicinal product if you have a known sensitivity, or if you have been advised not to work with such a product.

2. Handle this veterinary medicinal product with extreme care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure to theproduct, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes, or breathing difficulty, are more serious symptoms and require urgent medical attention.

Wash hands after use.

Additional precautions

Cobactan 2.5% Veterinary is selective for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) which may constitute a risk to human health if these strains disseminate to humans e.g. via food. **Use of Cobactan 25 mg/ml may constitute a risk to public health due to spread of antimicrobial resistance.**
Cobactan 2.5 veterinary should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given, may increase the prevalence of resistance. Whenever possible, Cobactan 2.5%veterinary should only be used based on susceptibility testing.

Pregnancy and lactation of the treated animal
There is no available information indicating reproductive toxicity in cattle and pigs. In

reproduction toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential.

Use only according to the benefit/risk assessment by the responsibleveterinarian.

Interactions with other medicines and other forms of interactions

It is known that a cross sensitivity to cephalosporin exists for bacteria sensitive to the cephalosporin group.

Due to undesirable pharmacodynamic interaction, do not apply cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

Overdose
Overdoses of 20 mg/kg/day in cattle and 10 mg/kg/day in pigs and piglets have been well tolerated.

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight 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 and protect from light.
- Use within 4 weeks of first opening date.

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

Dispose of any unused product.
Any unused veterinary product or waste materials derived from veterinary product use should be disposed of as toxic waste; do not discard into the wastewater.

13. FURTHER INFORMATION:

- In addition to the active ingredient, the medicine also contains: Ethyl oleate
- What does the medicine look like and what are the contents of the package:

  Milky-white to light brown suspension.
  Type II glass vials sealed with a stopper.

- The package contains one 50 ml or 100 ml vial.
- Not all pack sizes may be marketed.
- **License holder and address:** Intervet Israel Ltd., Hod HaSharon 45240, Israel.
- **Manufacturer name and address:**

  Intervet International GmbH,

  Feldstrasse 1 A, 85716 Unterschleissheim, Germany

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 082-71-92313-00