Consumer leaflet for a Veterinary Product
This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. CEFACTAN 25 MG/ML VETERINARY Suspension for Intramuscular Injection (I.M)

2. COMPOSITION:

Each 1 ml contains:
Active ingredient:
CEFQUINOME (AS SULFATE) 25 MG / 1 ML

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

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, necrosis infectious bulbar 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 bacteria.
2. Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E. coli, Staphylococcus spp.,* and other cefquinome-sensitive bacteria.

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 bacteria.
3. Epidermitis (mild to moderate lesions) caused by *Staphylococcus hyicus.*

4. CONTRAINDICATIONS:

- Do not inject cefquinome into animals with a known sensitivity 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.

- Do not use Cefactan 25 MG/ML Veterinary in poultry (including eggs) due the risk of creating resistance to antibiotics in humans.

5. SIDE EFFECTS:

Use of the product may cause a localized tissue reaction. This reaction will disappear within 15 days following the last injection.
Hypersensitivity reactions to cephalosporins are rare.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively, you can use the following link: https://sideeffects.health.gov.il

6. TARGET ANIMALS:

Cattle, pigs, piglets

7. METHOD OF ADMINISTRATION AND DOSAGE:

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.
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

Cefactan 25 MG/ML Veterinary is intended for treatment of specific animals. Do not use Cefactan 25 MG/ML Veterinary for disease prevention or as a part of herd health programme.

Use of Cefactan 25 MG/ML Veterinary for treatment of groups of animals should be strictly restricted to ongoing disease outbreaks only, according to the approved instructions for use.

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

1. Do not handle this product if you have a known sensitivity, or if you have been advised not to work with such a product.
2. Handle this product with extreme care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure to the product, such as skin rash, consult a doctor and show him this warning. Swelling of the face, lips or eyes, or breathing difficulty, are more serious symptoms and require urgent medical attention.
4. Cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, swallowing or skin contact. Hypersensitivity to penicillins may lead to cross-sensitivity to cephalosporins and vice versa.
   Allergic reactions to these substances may sometimes be serious.

Additional precautions

Cefactan 25 MG/ML Veterinary is selective for resistant strains such as bacteria carrying extended spectrum beta-lactamases (ESBL) which may constitute a risk to human health if spread to humans e.g., via food.

For this reason, Cefactan 25 MG/ML Veterinary should be used in medical conditions which have responded poorly, or are expected not to respond (in acute cases when treatment must be initiated without bacteriological diagnosis), to first line treatment. Local regulations (if they exist) should be taken into account when administering antimicrobial medicines to farm animals.

Increased use, including deviation from the instructions for use in the leaflet, may increase the prevalence of such resistance.
Whenever possible, use of Cefactan 25 MG/ML Veterinary should be based on susceptibility testing.

Pregnancy and lactation
There is no information indicating reproductive toxicity in cattle and pigs. Use only according to the benefit/risk assessment of the veterinarian.

Interactions with other medicines and other forms of interactions
Due to undesirable pharmacodynamic interaction, do not administer cefquinome simultaneously with bacteriostatic products.

There is a cross-sensitivity to cephalosporins for bacteria sensitive to the cephalosporin group.

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 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 and protect from light.
- Use within 4 weeks of opening date.
- Dispose of any remaining product.

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

Do not discard any remainders of medicines 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: Ethyl oleate
- What does the medicine look like and what are the contents of the package:
  Yellowish homogeneous suspension.
  Glass vials sealed with rubber stopper.

- The package contains one 100 ml vial.
- **License holder and address:** ROMAT Ltd., HA'MAAPILIM 39/104, HERZLIYA 46543, Israel.
- **Manufacturer name and address:**
  FATRO S.P.A., ITALY
  VIA EMILIA 285 - 40064, OZZANO EMILIA, BOLOGNA, ITALY

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 172-11-35763-00

Revised in May 2023 according to MoHs guidelines.