

Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. Name, form and strength of the veterinary medicine

Cefactan 25 mg/ml Veterinary

Suspension for Intramuscular Injection (I.M)

2. Active ingredients and quantity in a single dose

Each 1 ml contains:

Active ingredient:

CEFQUINOME (AS SULFATE) 25 MG

(Equivalent to 29.64 mg/ml Cefquinome sulfate)

A list of inactive ingredients is detailed in section 13 "Additional 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, 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 use in animals, which are known to be hypersensitive to β -lactam
- 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 Cefactan 25 MG/ML Veterinary in poultry (including eggs) due to the risk of spreading antibiotic resistance in human.

5. Side effects

Use of the veterinary medicinal product may result in a localized tissue reaction. Tissue lesions are repaired within 15 days after the last injection administration of the veterinary medicinal product.

Hypersensitivity reactions to cephalosporins are rare.

If you notice any serious side effects or other side effects not mentioned in this leaflet, please inform the veterinarian.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to medical treatment," located in the Ministry of Health homepage:

(<https://www.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 <i>Pasteurella multocida</i> and <i>Mannheimia haemolytica</i>	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 <i>E. coli</i> 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	<i>E. coli</i> 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. Instructions for use of the preparation

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. Warnings

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 program.

The treatment of groups of animals should be strictly restricted to ongoing disease outbreaks, according to the approved instructions 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 the product, 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

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 these strains disseminate to humans e.g., via food. **Use of Cefactan 25 MG/ML**

Veterinary may constitute a risk to public health due to the potential for the spread of antimicrobial resistance.

Cefactan 25 MG/ML 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, Cefactan 25 MG/ML Veterinary should only be used based on susceptibility testing.

Pregnancy and lactation

There is no 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 responsible veterinarian.

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 28 days of the first opening date.

12. Instructions for the disposal of the preparation/preparation residues 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. Additional 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.
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 January 2025.