

Only for Veterinary Use

# Cephanom<sup>®</sup> %5

Suspension for Injection

Veterinary Systemic Antibacterial

## COMPOSITION

Cephanom 5% Suspension for Injection is a white – light cream sterile suspension which contains 59.28 mg cefquinom sulphate equivalent to 50 mg cefquinom per ml.

## PHARMACOLOGICAL PROPERTIES

The active ingredient of Cephanom, cefquinom, is a 4<sup>th</sup> generation, wide-spectrum and Beta-lactamase resistant cephalosporin which exerts bactericide effect. Cephalosporins kill bacteria by inhibiting synthesis of cell wall in bacteria. It has wide-spectrum involving many Gram positive and Gram negative bacteria including Beta-lactamase positive and penicillinase positive bacteria. Bacteria susceptible to cefquinom included Gram positive and Gram negative bacteria such as *Escherichia coli*, *Citrobacter spp.*, *Klebsiella spp.*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Proteus spp.*, *Salmonella spp.*, *Serratia marcescens*, *Haemophilus somnus*, *Arcanobacterium pyogenes*, *Bacillus spp.*, *Corynebacterium spp.*, *Staphylococcus spp.*, *Streptococcus spp.*, *Bacteroides spp.*, *Clostridium spp.*, *Fusobacterium spp.*, *Prevotella spp.*, *Actinobacillus spp.*, *Erysipelothrix rhusiopathiae*.

*Rhodococcus spp.* are *Pseudomonas spp.* are moderately susceptible to cefquinom, whereas *Campylobacter spp.* are *Enterococcus spp.* are resistant.

When it is intramuscularly administered to cattle at dose of 1 mg/kg live body weight, peak serum concentration (approx. 2 µg/mL) is reached within 1.5 – 2 hours. Serum half elimination time of cefquinom is around 2.5 hours. Concentration is higher in bronchial secretions relative to plasma levels. It is bound to plasma proteins by 5 - 15 percent. It is excreted via urine.

## AREA OF USE/INDICATIONS

**Cephanom is used for bacterial infections in cattle and calf resulting from susceptible Gram negative and Gram positive bacteriae.**

- Respiratory tract infections resulting from *Pasteurella multocida* and *Mannheimia haemolytica*
- Digital dermatitis, infectious bulbar necrosis and acute interdigital necro-bacillosis
- Systemic acute mastitis
- E.coli septicemias in calf.

## AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Cephanom 5% Suspension for Injection is intramuscularly administered at dose of 1 mg/kg live body weight. Practical dose is administered at dose of 1 ml/50 kg live body weight. Frequency of re-administration is once every 24 hours. Treatment period is 3-5 days. Two administrations are made in 24-hour intervals for treatment of mastitis. Before use, agitate bottle well and thus, suspension is homogenized.

## ADVERSE / SIDE EFFECTS

Transitional tissue reactions may occur in injection site following intra-muscular administration. Anaphylactic reactions may develop in animals hypersensitive to penicillin and cephalosporins.

## **DRUG INTERACTIONS**

Cephalosporins are antagonistic to tetracyclines and other bacteriostatic antibiotics. It has synergistic effect with aminoglycosides.

## **SYMPTOMS, PRECAUTIONS AND ANTIDOTE IN OVERDOSE**

Systemic toxicity reactions were not observed secondary to administration of high doses to cattle. No toxicity reaction was observed in cattle at doses 10 folds therapeutic dose.

## **WARNINGS FOR THE DRUG RESIDUES IN NUTRIENTS**

***Withholding Period (WHP): Cattle should not be transferred to slaughtering throughout the treatment or within 5 days following last administration of the drug. Withholding Period is 1 day (2 milking) for milking cow.***

## **CONTRAINDICATIONS**

It should not be used in animals sensitive to penicillin and derivatives. Intravenous administration is contraindicated.

### **Usage in pregnancy**

Embryotoxic and teratogenic effects were not observed in studies conducted on rats and rabbits.

## **GENERAL WARNINGS**

Please refer to the veterinary surgeon before use and in case of an unexpected effect. **Keep out of the reach of children.**

## **PRECAUTIONS TO BE TAKEN BY ADMINISTRATOR AND WARNING FOR VETERINARY SURGEON:**

Contact of penicillin and cephalosporin with allergic subjects via injection, inhalation, digestion and direct contact may lead to allergic reactions (hypersensitization). Allergic reactions to those substances may sometimes lead to serious health problem. Therefore; these groups of drugs should not be administered to subjects with known allergy to penicillin and cephalosporin.

- Necessary precautions should be taken in order not to contact with the drug during administration.
- If allergic symptoms such as pustules occur due to contact with the drug, a doctor should be contacted. Facial, ocular and lip swelling and breath shortness are more serious symptoms which require emergency intervention.

## **STORAGE CONDITIONS AND SHELF LIFE**

Store at room temperature (15-25°C) away from sun light and it should not be frozen. It should be used within 4 weeks after original bottle is opened. Shelf life is 2 years from the date of production.

## **COMMERCIAL SUPPLY INDICATING COMPOSITION AND QUANTITY OF PACKAGING**

Cephanom 5% Suspension for Injection is commercially available in 20, 50 and 100 ml colorless glass vials packed into cardboard boxes as well as 250 ml colorless glass vials packed into plastic box.

## **SALE PLACE AND CONDITIONS**

**It is sold in the veterinary offices and the pharmacies with prescription of veterinary surgeon (VP).**

**PROSPECTUS APPROVAL DATE: 02.02.2011**

**DATE AND NUMBER OF LICENSE AWARDED BY THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS:** 24.01.2011-23/071

**NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:**

**Alke Saęlık Ürünleri San. ve Tic. A.Ş**

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**NAME AND ADDRESS OF MANUFACTURER COMPANY:**

**Alke Saęlık Ürünleri San. ve Tic. A.Ş**

Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat