Leaflet

For Veterinary Use Only

CEFTIVIL

Suspension for Injection

Veterinary Systemic antibacterial

COMPOSITION

Ceftivil is a sterile suspension that is white or cream-colored, containing 50 mg of Ceftiofur.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Ceftiofur is a 3rd generation cephalosporin that is effective against most Gram positive and Gram negative bacteria.Ceftiofur exerts its effect by inhibiting bacterial cell wall synthesis.Beta-lactams exert their effect by interfering with bacterial cell wall synthesis. Cell wall synthesis depends on enzymes called penicillin-binding proteins. Bacteria develop resistance to cephalosporins through four main mechanisms: 1) By making penicillin-binding proteins insensitive, 2) By altering the permeability of the cell wall to beta-lactams, 3) By producing beta-lactamases that break down the beta-lactam ring, 4) Active efflux.

Some beta-lactamases found in Gram-negative enteric organisms can increase the MIC values of first- and second-generation cephalosporins, beta-lactam-inhibitor combinations, penicillins, ampicillins, and third- and fourth-generation cephalosporins by variable amounts.

MIC values of target bacteria obtained from infected animals in Europe are as follows:

Bacteria (number of isolates)	**MIC range (µg/mL)**	**MIC_{90} (µg/mL)**
Mannheimia haemolytica (149)	0.002 - 0.12	0.015
Pasteurella.multocida (134)	0.002 - 0.015	0.004
Histophilus somni (66)	0.002 - 0.008	0.004
Truperella pyogenes (35)	0.25 - 4	2
Escherichia coli (209)	0.13 - 2	0.5
Fusobacterium necrophorum (67)(Foot rot isolates)	0.06 - 0.13	TE
Fusobacterium necrophorum (2)(acute metritis isolates)	0.03 - 0.06	TE

TE: could not be detected.

The Clinical and Laboratory Institute has recommended the following values for the pathogens listed on the label for ceftiofur.

Zone Diameter (mm)	**MIC (µg/mL)**	**Rating**
≥ 21	2.0	(S) Susceptible-Sensitive
18 - 20	4.0	(I) Intermediate- Moderately Sensitive
17	≥ 8.0	(R) Resistant- Resistant

Pharmacokinetics Properties

After administration, ceftiofur is rapidly metabolized to its main metabolite, desfurilceftiofur.
This metabolite has the same antimicrobial activity as ceftiofur. It reversibly binds to plasma proteins. Due to its binding to these proteins, the metabolite actively participates at the site of infection and remains active in the presence of pus and necrotic tissue.
In cattle, after a single subcutaneous dose of 1 mg/kg, the maximum plasma level (2.85 ± 1.11 µg/mL) was reached two hours after administration. In healthy cattle, after a single administration, the Cmax level in the endometrium was measured at 2.25 ± 0.79 µg/mL, approximately 5±2 hours later. The maximum concentration in the oviduct and the cervix were measured at 1.11 ± 0.24 µg/mL and 0.98 ± 0.25 µg/mL, respectively.
The half-life in cattle is 11.5 ± 2.57 hours. No accumulation was observed with daily treatments lasting longer than five days. Excretion occurs primarily via urine (more than 55%) and feces (31%).
Ceftiofur has complete bioavailability after subcutaneous administration.

AREA OF USE/INDICATIONS

Cattle and swine are sensitive to ceftiofur;

- Treatment of respiratory system infections caused by Mannheimia haemolytica (formerly Pasteurella haemolytica), Pasteurella multocida, and Histophilus somni (formerly Haemophilus somnus) strains,
- Treatment of acute interdigital necrobacillosis (panaritium, foot rot) caused by Fusobacterium necrophorum and Bacteroides melaninogenicus (Porphyromonas asaccharolytica),
- Treatment of acute postpartum (puerperal) metritis caused by Escherichia coli, Arcanobacterium pyogenes, and Fusobacterium necrophorum, when treatment with other antibiotics has been unsuccessful, within 10 days after calving.

In pigs; For the treatment of bacterial respiratory disease associated with Pasteurella multocida, Actinobacillus pleuropneumoniae and Streptococcus suis.

USAGE AND DOSAGE

Before use, shake the bottle vigorously for no more than 60 seconds or until fully suspended.
For accurate dosing, the body weights of the animals should be measured as precisely as possible.
Respiratory system infections: Subcutaneous administration at a dose of 1 mg/kg body weight per day for 3-5 days (1 ml of product per 50 kg body weight per day).
Acute interdigital necrobacillosis: Subcutaneous administration at a dose of 1 mg/kg body weight per day for 3 days (1 ml of product per 50 kg body weight per day).
Acute post-partum metritis (within 10 days after calving): Subcutaneous administration at a dose of 1 mg/kg body weight per day for 5 days (1 ml of product per 50 kg body weight per day). In some cases of this infection, supportive treatment may be required.
A maximum of 15 ml should be injected into a single injection site. Injections on different days should be made at different sites.
Swine: 3 mg/kg body weight (1 ml/16 kg body weight) intramuscularly or subcutaneously for 3 days.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

Shake the bottle well before use to return it to suspension form.

If an allergic reaction is observed, treatment should be discontinued.

This product is selective for resistant strains producing extended-spectrum beta-lactamases, which may pose a risk to human health (e.g., via food consumption). Therefore, this product should be reserved as an antibiotic for cases where initial treatment has had poor results or is expected to have poor results (severe acute conditions where treatment must be started without a bacteriological diagnosis).

Regional and national antimicrobial policies should be considered when using this product. The increased use of this product, including use in a manner different from what is specified in this document, may lead to an increase in the prevalence of resistant bacteria. Therefore, this product should be used according to sensitivity test results whenever possible.

It is not to be used for preventive purposes in cases of placental retention.

This product is for individual treatment. It is not to be used as part of disease prevention or herd health programs. The treatment of animals in groups should only be limited to epidemic diseases and must comply with approved usage conditions.

Use during pregnancy: Studies conducted in laboratory animals have not shown teratogenicity, abortion, or reproductive effects; however, the safe use of the product in pregnant cows has not been studied. It may only be used during pregnancy based on the veterinarian's benefit/risk assessment.

ADVERSE EFFECTS

Dose-independent hypersensitivity reactions may occur. Allergic reactions (such as skin reactions, anaphylaxis) have been reported very rarely (less than 1 in 10000 animals).

In cattle, swelling and hardness at the injection site have been observed after subcutaneous administration. Local tissue reactions (edema, discoloration, etc.) ranging from mild to moderate have been observed up to 42 days after injection. According to field reports, injection site reactions are very rare.

DRUG INTERACTIONS

The bactericidal effect of beta-lactams is inhibited by bacteriostatic antibiotics such as macrolides, sulfonamides, and tetracyclines. Aminoglycosides positively affect the efficacy of cephalosporins. It should not be mixed with other products.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

In cattle, no significant signs of systemic toxicity have been observed in cases of parenteral overdose.

WITHDRAWAL PERIODS

Meat: 8 days for cattle, 5 days for pigs.

Milk: '0' days.

CONTRAINDICATIONS

It should not be administered to animals known to be sensitive to ceftiofur or beta-lactams.

It should not be administered intravenously.

It should not be used in cases where resistance to other cephalosporins or beta-lactams has

developed.
It should not be used in chickens, including laying hens, due to the risk of antimicrobial resistance posing a threat to human health.

GENERAL WARNINGS
Consult a veterinarian before use and if any unexpected effects occur. Keep out of reach of children.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON
Penicillins and cephalosporins can cause hypersensitivity (allergic) reactions following injection, inhalation, oral administration, or skin contact. Sensitivity to penicillins can lead to sensitivity to cephalosporins (and vice versa). These reactions are rarely very serious.
If you are sensitive and have been medically advised not to work with such products, do not handle this product.
If symptoms such as redness of the skin develop, seek medical treatment immediately and show this warning to the healthcare provider. Take necessary precautions to avoid accidentally injecting the product. In such cases, seek medical attention immediately at a healthcare facility.
Symptoms such as swelling of the face, lips, or eyes, or difficulty breathing, are very serious and require immediate medical treatment.
Wash your hands after use.

STORAGE CONDITIONS AND SHELF LIFE
Before and after opening, it should be stored in the original packages, protected from light, and below 25°C, without being placed in the refrigerator or freezer. The shelf life is 2 years. It should be used within 30 days after the first use.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES
Used or remaining product should be disposed of according to the relevant regulations.

COMMERCIAL PRESENTATION FORM
50 ml, 100 ml, and 250 ml amber-colored glass vials with cardboard boxes.

PLACE AND CONDITIONS OF SALE
It is sold in pharmacies and veterinary clinics with a veterinarian's prescription. (VHP)

APPROVAL DATE OF LEAFLET: 22.02.2023

MARKETING AUTHORIZATION DATE AND NO: 01.09.2006 – 16/077
NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER
VILSAN Veteriner İlaçları Tic. Ve San. A.Ş.
Balıkhisar Mah, Balıkhisar Köyiçi Küme Evleri No: 765A, Akyurt/Ankara – Türkiye
MANUFACTURER COMPANY
VILSAN Veteriner İlaçları Tic. Ve San. A.Ş.
Balıkhisar Mah, Balıkhisar Köyiçi Küme Evleri No: 765A, Akyurt/Ankara – Türkiye

Made in Turkiye

Box

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