For Veterinary Use Only

Ceftipure®

Suspension for Injection

Veterinary Systemic Antibacterial

COMPOSITION

Ceftipure Suspension for Injection is a light cream – white suspension containing ceftiofur hydrocloryde equivalent to 50 mg ceftiofur per ml.

PHARMACOLOGICAL PROPERTIES

Ceftiofur is a third generation wide-spectrum cephalosporin acting bacteriodal, and is resistant to β-lactamase enzymes. Cephalosporins kills bacteria by preventing cell wall synthesis in bacteria. Its antibacterial influence area comprises Gram positive and Gram negative bacteria.

Effects of Ceftiofur on bacteria is as follows.

Bacteria whose sensitivity is higher (MIC <2µg /ml): Streptococcis (excluding eterococcus), number of gram positive bacteria which are sensitive to benzyle penicillin, E. coli, Klebsiella sp., Proteus sp. ve Salmonella sp., including beta-lactamase producers Antinobacillus sp., Haemophilus sp., Pasteurella sp., Clostridium sp. and Fusobacterium sp.

Bacteria whose sensitivity is at moderate level (MIC 4µg /ml): Staphylococcus aureus, some Citrobacter sp., Eterobacter sp., some Pseudomonas aeruginosa strain and Serratia sp.

Resistant bacteria (MIC > 8 µg /ml): Acinetobacter sp., Bordetella sp., some Enterobacter sp., and Serratia sp. some Pseudomonas aeroginosa strains, Staphylococus aureus strains resistant to enterococci and methiciline.

Ceftiofur reaches to its maximum blood concentration within 1 to 4 hours (11±1.69 µg /ml) when intramuscular application, and within 1 to 5 hours (8.56± 1.89 µg /ml) when subcutaneous application. Half life is 12 ± 2.63 hours after intramuscular application, and 11.5±2.57 hours after subcutaneous application. Plasma concentration has been reported at the end of the 24 hours as 1.47 µg /ml when applying intramuscularly, and as 0.926 µg /ml when administering subcutaneously. Plasma concentration has been reported at the end of the 48 hours as 0.34 µg /ml when applying intramuscularly, and as 0.271 µg /ml when administering subcutaneously. Any concentration after 48 hours is higher than needed MIC values considering >Mannhemia sp. (Pasteurella Haemolycita), Pasteurella multocida, Heamophillus somnus, and Fusobacterium necrophorum.

Ceftiofur is converted to the main metabolite desfuroylceftiofur after the application. It is highly disturbed to tissues. A 60-80% of it is excreted through urination, and the rest through gaita.

AREA OF USE/INDICATIONS

Ceftipure Suspension for Injection is used in treatments for respiratory and soft tissue infections which are formed by bacteria sensitive to ceftifur in cattle. Ceftipure Suspension for Injection is used for

respiratory infections caused by Mannhemia sp. (Pasteurella haemolytica), Pasteurella multocida, Heamophillus somnus in cattle.

In acute interdigital necrobasillosis (commissura ecchymosis, pododermatitis) caused by fusobacterium necrophorum and Bacteriodes melaninogenicus.

It's used in postnatal acute puerperal metritis caused by E.coli, Arconobacterium pyogenes, and Fusobacterium necrophorum.

USAGE AND DOSAGE

Ceftipure Suspension for Injection is allowed to be used at 1 mg/kg of live weight dosage intramuscularly and subcutaneously in cattle.

Its Practise Dose is administered as 1 ml / 50 kg live weight. Prevalence is once 24 hours. Treatment term is for 3 days, in case of not obtaining any results that treatment may be prolonged for more 2 days. When large volume applications are needed, the total dose is to be administered after being separated to some volumes of 15 ml. Suspension should be homogenised before use by strongly shaking the bottle. Intravenous application is contraindicated .

UNDESIRED/SIDE EFFECTS

Temporary tissue reactions may arise on injection area after intramuscular and subcutaneous application. Anaphylactic reactions may be arisen in animals hypersensitive to penicillin and cephalosporin.

DRUG INTERACTIONS

Cefalosporins are antagonist to tetracyclins and other bacteriostatic antibiotics. They effect synergistically along with aminogylcoside

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

No systemic toxicity reactions due to high dose application in cattle. Ceftiofur is administered to calfs in 55 mg/kg live weight dose for 5 days, and no side-effect was observed.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding period (WHP): Cattle should not be sent for slaughtering during treatment and before 7 days after the last drug administration. Residue purification time for milk is “0” days.

CONTRAINDICATIONS

Avoid administrating in animals with hypersensitivity to penicillin and derivatives. Avoid administrating in animals with serious renal defects.

Use during pregnancy:

Studies on experimental animals have revealed that 1000 mg/kg live weight/day dose effects on reproductive performance, and no teratogenic effect was seen. Reliability of ceftiofur on pregnant cows is not studied specifically.

GENERAL WARNINGS

Consult your veterinary surgeon before using and in case an unexpected effect is observed. Keep out of reach of children.

MEASURES BY ADMINISTRATOR, AND GENERAL WARNING Penicillin and cephalosporin may cause allergic reactions (hypersensitization) by infecting sensitive people through injection, inhalation, digestion, and contact. Sometimes allergic reactions due to those substances may cause serious health problems. Therefore;

* Individuals known with penicillin and cephalosporin allergy should avoid administering those drug groups.
* Required measures have to be provided in order to avoid any contact with the drug during its administration.
* If any allergic symptoms including roseola occur as a result of contact with drug, seek for medical assistance. In case of more serious symptoms including swelling of face, lips and eyes or respiratory distress, seek for medical assistance immediately.
* In case of any contact with eyes accidentally, eyes should be washed for 15 minutes.

WARNINGS FOR NON-TARGET SPECIES

Avoid administration in rabbits and hamster. Besides avoid administration in snakes and poultry with totipalmate (e.g. duck, goose).

Administration in horses may cause gastrointestinal disturbances including colitis.

STORAGE CONDITIONS AND SHELF LIFE

The product should be stored at room temperature (15 – 25oC) and should be protected from light, and should not be frozen. Shelf life after initial use is for 30 days as long as it is kept under 25 oC. Shelf life is 2 years as of the production date.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE

It is offered for market in cardboard boxes containing colourless amber vials of 20, 50, 100 and 250 ml.

PLACE AND CONDITIONS OF SALE

Sold with Veterinary Surgeon’s prescription in pharmacies and veterinary surgeries. VSP

APPROVAL DATE OF PACKAGE INSERT: 03.07.2008

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS AUTHORIZATION DATE AND NO : 03/07/2008/-20-021

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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