

Cencure 50mg/ml Powder for Injection

Active substance: Each bottle contains ceftiofur (as sodium ceftiofur) 4gram.
Each ml of reconstituted solution contains ceftiofur 50mg.

Product Description: Faint yellow or yellowish powder

Pharmacodynamics: It contains sodium ceftiofur, a broad-spectrum cephalosporin which is active against Gram-positive and Gram-negative bacteria, including beta-lactamase producing strains. Ceftiofur has bactericidal activity in vitro. The mode of action is that of cephalosporins, i.e. inhibition of the bacteria cell wall synthesis.

Pharmacokinetics: After intramuscular administration ceftiofur is quickly metabolized to desfuroylceftiofur which reaches its maximum plasma concentration within 1 hour. The half-life of desfuroylceftiofur is on average greater than 9 hours in cattle and 13 hours in pigs. No accumulation has been shown after several administrations.

Indication: Ceftiofur sodium is indicated for treatment of bovine bacterial respiratory disease associated with Mannheimia haemolytica, Pasteurella multocida, and Actinobacillus (Haemophilus) somnus and other sensitive bacterial pathogens. For the treatment of cattle with acute interdigital necrobacillosis (foul in the foot) in which Fusobacterium necrophorum and Bacteroides melaninogenicus are involved. The treatment of pigs with bacterial respiratory disease in which Actinobacillus (Haemophilus) pleuropneumonia, Pasteurella multocida and Streptococcus suis are involved.

Recommended Dosage: Dissolve the 4 g sterile powder in 80 ml of Water for Injection. Rapid addition of diluent will give best results. The resulting solution contains 50 mg ceftiofur free acid equivalents per ml. For ease of reconstitution use an 18-gauge needle.

Cattle: 1 mg/kg bodyweight. This is equivalent to 1 ml of the reconstituted solution per 50 kg bodyweight. For respiratory disease, the dose should be given once daily at 24 hour intervals for 3 to 5 days in total. For interdigital necrobacillosis (foul in the foot), the dose should be given once daily at 24 hour intervals for 3 days. As with all antibiotic therapy, treatment of this condition should be instituted as early as possible in order to provide maximum clinical benefit.

Pigs: 3 mg/kg bodyweight: This is equivalent to 1 ml of the reconstituted solution per 16 kg bodyweight. The dose should be given once daily at 24 hour intervals for 3 days. If no response is seen within these periods, the diagnosis should be redetermined. Administration: The intramuscular route only should be used in cattle and pigs.

Contraindications: As for all antibiotics, do not administer to animals previously found to be hypersensitive to the active ingredient. Do not use in poultry (including eggs) due to the risk of spread of antimicrobial resistance to humans.

Warnings and Precautions: Special precautions for use in animals- It selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, it should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) 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 such resistance. Whenever possible, it should only be used based on susceptibility testing. It is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals- Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, seek medical advice immediately. 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. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this product with great care to avoid exposure taking all recommended precautions. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

Interactions with Other Medicaments: None known.

Pregnancy & Lactation: No data available for cattle. In rats no teratogenic signs, abortion or influence on reproduction have been observed

Adverse Effects/Undesirable Effects: General symptoms are not detected. The use of ceftiofur sodium may result in some signs of immediate and short-lasting pain at the site of injection.

Overdose and Treatment: None known **Incompatibility:** None known

Withdrawal Period(s): Meat: Cattle - 1 day. Pigs - 2 days Milk: Cattle - Zero hours

Dosage Forms and packaging available: 4g powder in bottle (with 80ml sterile water for injection in bottle).

Storage: Store at 25°C before reconstitution. Protect from light.

Shelf life after reconstitution: Use within 12 hours if stored at 20-25°C, use within 7 days if stored at 2-8°C and use within 8 weeks if stored frozen.

Name and address of manufacturer:

CTCBIO INC. Office: CTC Bldg, 13, Jungdae-ro, 40-gil, Songpa-gu, Seoul, Korea South

Plant: 94, Saengmyeongwahakgwang-gil, Hongcheon-eup, Hongcheon-gun, Gangwon-do, Korea South

Name and address of marketing authorization holder:

QL Pacific Vet Group Sdn Bhd.

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Date of Revision of Package Insert: 21 December 2020

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