

Each mL of reconstituted solution contains:

Ceftiofur sodium equivalent to 50 mg ceftiofur.

Reconstitute by adding 80 mL of sterile diluent for **EXCENEL** sterile powder to each 4 g vial.

Product Description:

Dry Cake: A white to light brown freeze-dried solid.

Reconstituted Product: A clear, brownish-yellow solution.

Pharmacodynamics: Excenel Sterile Powder 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:

Dogs: EXCENEL Sterile Powder is indicated for the treatment of canine urinary tract infections associated with *Escherichia coli* and *Proteus mirabilis*.

Recommended dose:

Dogs: Administer to dogs by subcutaneous injection at the dosage of 1.0 mg ceftiofur per pound (2.2 mg/kg) of body weight (0.1 mL reconstituted sterile solution per 5 lbs body weight). Treatment should be repeated at 24-hour intervals for 5-14 days. Reconstituted EXCENEL Sterile Powder is to be administered to dogs by subcutaneous injection. No vial closure should be entered more than 20 times. Therefore, only the 1 gram vial is approved for use in dogs.

Incompatibilities:

None known.

Route of Administration:

Dogs: Administer to dogs by subcutaneous injection

Contraindications: As with all drugs, the use of EXCENEL Sterile Powder is contraindicated in animals previously found to be hypersensitive to the drug

Warnings and Precautions: Penicillins and cephalosporins can cause allergic reactions in sensitized individuals. Topical exposures to such antimicrobials, including ceftiofur, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact of the product with the skin, eyes, mouth, and clothing. Persons with a known hypersensitivity to penicillin or cephalosporins should avoid exposure to this product. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. If allergic reaction occurs (e.g., skin rash, hives, difficult breathing), seek medical attention.

Interaction with Other Medicaments: None known.

Pregnancy and Lactation:

Dogs: The safety of ceftiofur has not been determined for dogs intended for breeding, or pregnant dogs.

Side 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.

Storage Condition:

Store un-reconstituted product in a refrigerator (2 to 8°C).

Store reconstituted product at 2 to 8°C for up to 7 days or at controlled room temperature (15°C to 30 °C) for up to 12 hours.

Packaging: 6 x 4 g vials

Manufactured by:

Zoetis Inc.

2605 East Kilgore Road, Kalamazoo, Michigan 49001, USA.

Product Registration Holder:

Zoetis Malaysia Sdn. Bhd.

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