EXCENEL® RTU STERILE SUSPENSION
Pfizer Animal Health

Ceftiofur hydrochloride sterile suspension

DESCRIPTION
For intramuscular and subcutaneous use in cattle and intramuscular use in swine. EXCENEL RTU Sterile Suspension is a ready to use formulation that contains the hydrochloride salt of ceftiofur, which is a broad spectrum cephalosporin antibiotic.

Each mL of this ready-to-use sterile suspension contains ceftiofur hydrochloride equivalent to 50 mg ceftiofur, 0.50 mg phospholipon, 1.5 mg sorbitan monooleate, 2.25 mg sterile water for injection, and cottonseed oil.

Structure:

INDICATIONS
EXCENEL RTU Sterile Suspension is indicated for treatment/control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with Actinobacillus (Haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis and Streptococcus suis.

WARNINGS
NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.
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.
When used according to label indications, dosage, and route of administration, treated swine must not be slaughtered for 4 days following the last treatment. Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in edible tissues.

**PRECAUTIONS**
The effects of ceftiofur on cattle and swine reproductive performance, pregnancy, and lactation have not been determined. Areas of discoloration associated with the injection site at time periods of 11 days or less may result in trim-out of edible tissues at slaughter. The safety of ceftiofur has not been demonstrated for pregnant swine or swine intended for breeding.

**SAFETY**
Results from a five-day tolerance study in normal feeder pigs indicated that ceftiofur sodium was well tolerated when administered at 57 mg ceftiofur equivalents/lb (125 mg/kg) (more than 25 times the highest recommended daily dosage of 2.27 mg/lb (5.0 mg/kg)) BW for five consecutive days. Ceftiofur administered intramuscularly to pigs produced no overt adverse signs of toxicity.

To determine the safety margin in swine, a safety/toxicity study was conducted. Five barrows and five gilts per group were administered ceftiofur sodium intramuscularly at 0, 2.27, 6.81 and 11.36 mg ceftiofur equivalents/lb (0, 5, 15, 25 mg/kg) BW for 15 days. This is 0, 1, 3 and 5 times the highest recommended dose of 2.27 mg/lb (5.0 mg/kg) BW/day and 5 times the recommended treatment length of 3 days. There were no adverse systemic effects observed, indicating that ceftiofur has a wide margin of safety when injected intramuscularly into feeder pigs at the highest recommended dose of 2.27 mg ceftiofur equivalents/lb (5.0 mg/kg) BW daily for 3 days or at levels up to 5 times the highest recommended dose for 5 times the recommended length of treatment.

A separate study evaluated the injection site tissue tolerance of EXCENEL RTU (ceftiofur hydrochloride) in swine when administered intramusculely in the neck at 1.36 and 2.27 mg ceftiofur equivalents/lb (3.0 to 5.0 mg/kg) BW. Animals were necropsied at intervals to permit evaluations at 12 h, and 3, 5, 7, 9, 11, 15, 20, and 25 days after last injection. Injection sites were evaluated grossly at necropsy. No apparent changes (swelling or inflammation) were observed clinically after 12 h post-injection. Areas of discoloration associated with the injection site were observed at time periods less than 11 days after last injection.

Radiolabeled residue metabolism studies established tolerances for ceftiofur residues in swine kidney, liver, and muscle. These tolerances of ceftiofur residues are 0.25 ppm in kidney, 3.0 ppm in liver and 2.0 ppm in muscle.

A pivotal tissue residue decline study was conducted in swine. In this study, pigs received 2.27 mg of ceftiofur per lb body weight (5 mg of ceftiofur per kg body weight) per day for three consecutive days. Ceftiofur residues in tissues were less than the tolerances for ceftiofur residues in tissues such as kidney, liver and muscle by 4 days
after dosing. These data collectively support a 4-day pre-slaughter withdrawal period in swine when used according to label directions.

**DIRECTIONS**
Store at controlled room temperature 20° to 25°C (68° to 77°F). Shake well before using. Protect from freezing.

**DOSES**
Shake well before using.
Administer intramuscularly at a dosage of 1.36 to 2.27 mg ceftiofur equivalents/lb (3.0 to 5.0 mg/kg) BW (1 mL of sterile suspension per 22 to 37 lb BW). Treatment should be repeated at 24 h intervals for a total of three consecutive days.