For Intramucosal injection in swine.

For Intramareral and subcutaneous injection in cattle. 

Swine: EXCENEL RTU EZ Sterile Suspension is a ready-to-use formulation that contains the hydrochloride salt of ceftiofur. It is in a broad spectrum cephalosporin antibiotic and is an anti-infective for the treatment of diseases caused by susceptible aerobic and anaerobic gram-negative bacteria. It is intended for pigs weighing more than 20 kg. The product is supplied as a coupon.
Sterile Suspension or as EXCENEL RTU EZ Sterile Suspension following Swine:

performance standards are used to determine antimicrobial susceptibility of bacteria associated with bovine foot rot. Pasteurella multocida, and Bacteroides melaninogenicus, are pathogens associated with large subcutaneous abscesses, and are considered to be in the family Pasteurellaceae. Methods: Ceftiofur has been demonstrated against a wide range of Gram-negative pathogens. The effectiveness of Ceftiofur against these Gram-negative pathogens is dependent upon time above MIC. Collectively, the data from these two studies support a 4-day pre-slaughter withdrawal period when used according to label directions.

STORAGE CONDITIONS
Store at controlled room temperature 20° to 25°C (68° to 77°F); excursions permitted 15° to 40°C (59° to 104°F). Protect from freezing. Shake well before using. Contents should be used within five days after the first dose.

How Supplied
EXCENEL RTU EZ Sterile Suspension is available in 100 mL and 250 mL. Distributed by: Zoetis Inc. Kalamazoo, MI 49007

Selected Interpretive Criteria for Ceftiofur

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Zone Diameter (mm)</th>
<th>MIC Breakpoint (μg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasteurella multocida</td>
<td>16</td>
<td>≥ 8.0</td>
</tr>
<tr>
<td>Actinobacillus lignihominis</td>
<td>21</td>
<td>≥ 4.0</td>
</tr>
<tr>
<td>Chlamydia pneumoniae</td>
<td>20</td>
<td>≥ 2.0</td>
</tr>
<tr>
<td>Pasteurella haemolytica</td>
<td>21</td>
<td>≥ 2.0</td>
</tr>
</tbody>
</table>

Interpretive criteria are only intended for use when CLSI M7-A11 performance standards are used to determine antimicrobial susceptibility.

EFFECTIVENESS

Swine: Plasma concentrations of ceftiofur administered as EXCENEL RTU Sterile Suspension or as EXCENEL RTU EZ Sterile Suspension following intramuscular administration in swine were compared and found to be bioequivalent for AUC0-LOQ and Cmax. Therefore, EXCENEL RTU EZ Sterile Suspension is considered equivalent for this treatment duration of swine respiratory disease. Ceftiofur residues in tissues such as the kidney and muscle by 4 days after dosing. These data collectively support a 4-day pre-slaughter withdrawal period when used according to label directions.

ANIMAL SAFETY

Swine: Evaluation of target animal safety in swine was based on a PK comparison between the reformulated EXCENEL RTU EZ Sterile Suspension and EXCENEL RTU Sterile Suspension. Cattle: Administration of EXCENEL RTU EZ Sterile Suspension by intramuscular injection at a dose of 2.2 mg CE/kg BW of the reformulated EXCENEL RTU EZ Sterile Suspension is considered safe for the treatment duration of cattle respiratory disease.

Radiolabeled residue metabolism studies established tolerances for ceftiofur residues in tissues such as the kidney and muscle by 4 days after dosing. These data collectively support a 4-day pre-slaughter withdrawal period when used according to label directions.

Tissue Residue Decline

Swine: A second injection site tolerance study was conducted in 10 young pigs with at least the maximum proposed volume of 5 mL per injection site once daily for three consecutive days. Each injection was administered in a different location on the neck, and was still present in both animals injected SC that were necropsied on Day 42. Grossly visible discoloration of the injection site and/or histopathologic changes consistent with inflammation were noted in treated pigs necropsied up to 42 days after injection. No test article-related health issues were observed. Mild swelling, erythema, and firmness were noted in treated pigs necropsied 7 days or 14 days after injection. A separate study established tolerances for ceftiofur residues in edible tissues. No test article-related health issues were observed. No test article-related health issues were observed. No test article-related health issues were observed. No test article-related health issues were observed.

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