See other side for instructions for use in horses.

ADMINISTRATION FOR THE MIDDLE THIRD OF THE EAR

Table 1. Dosing Schedule for EXCEDE Sterile Suspension.

<table>
<thead>
<tr>
<th>Cattle Type</th>
<th>Dosing Schedule</th>
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<tbody>
<tr>
<td>Beef - Middle</td>
<td>3.0 mg CE/lb (6.6 mg CE/kg) BW</td>
</tr>
<tr>
<td>Dairy Cow - Standard</td>
<td>3.0 mg CE/lb (6.6 mg CE/kg) BW</td>
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</tbody>
</table>

In a residue study, six dairy cows were injected in the base of the ear at a dose rate of 3.0 mg CE/lb (6.6 mg CE/kg) BW. Results from this study indicate that the subcutaneous injection of EXCEDE Sterile Suspension administered in the middle third of the posterior aspect of the ear may be effective for the treatment of clinical and subclinical BRD caused by Histophilus somni or Mannheimia haemolytica.

Intra-arterial injection of EXCEDE Sterile Suspension demonstrates bacterial killing at concentrations of 0.008 μg/mL (MIC50) and 0.004 μg/mL (MIC90) for Histophilus somni.

The pharmacokinetic parameters for the two subcutaneous locations of injection evaluated in a 15-location field effectiveness study. A total of 1023 cows with a fetid vaginal discharge and had no or mild depression on that day.

In vitro studies with cell culture isolates of Histophilus somni and Mannheimia haemolytica demonstrate that EXCEDE Sterile Suspension is bactericidal at concentrations of 0.008 μg/mL (MIC50) and 0.004 μg/mL (MIC90).

Topical exposures to such antimicrobials, including ceftiofur, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitivity reactions.

In a 15-day safety/toxicity study, five steer and five heifer calves per group were administered a two-dose regimen of EXCEDE Sterile Suspension at a dose rate of 3.0 mg CE/lb (6.6 mg CE/kg) BW. There were no adverse systemic effects, indicating that the subcutaneous injection of EXCEDE Sterile Suspension administered in the middle third of the posterior aspect of the ear may be therapeutically equivalent.

The local tolerance of the ear of cattle to a single subcutaneous injection of EXCEDE Sterile Suspension is evaluated through histopathological examination of injection sites. Through Day 14 after injection, injection volumes of 2.0 mL and 3.0 mL resulted in injection site thicknesses of 1.33 ± 0.13 mm and 1.24 ± 0.16 mm, respectively. Additional increases in thickness were observed through Day 14 after injection.

In a residue study, 72 beef cattle were injected in the base of the ear with EXCEDE Sterile Suspension administered subcutaneously in the middle third of the posterior aspect of the ear. The pharmacokinetic parameters for the two subcutaneous locations of injection are presented in Table 3. The pharmacokinetic parameters for the two subcutaneous locations of injection were similar.

Based upon the results of this relative bioavailability study, it was determined that the subcutaneous injection of EXCEDE Sterile Suspension administered in the middle third of the posterior aspect of the ear may be therapeutically equivalent.

In a 15-day safety/toxicity study, five steer and five heifer calves per group were administered a two-dose regimen of EXCEDE Sterile Suspension at a dose rate of 3.0 mg CE/lb (6.6 mg CE/kg) BW. There were no adverse systemic effects, indicating that the subcutaneous injection of EXCEDE Sterile Suspension administered in the middle third of the posterior aspect of the ear may be therapeutically equivalent.