**TECHNICAL BULLETIN**

Comparative efficacy of DRAXXIN® or Nuflor® for the treatment of undifferentiated bovine respiratory disease in feeder cattle

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**KEY POINTS**

- DRAXXIN® (tulathromycin) Injectable Solution administered as a single subcutaneous (SC) injection was safe and effective for the treatment of undifferentiated bovine respiratory disease (BRD). DRAXXIN was significantly more effective, in 2 studies with feeder cattle, than was Nuflor® (florfenicol) Injectable Solution.

- First-treatment success, in both studies, for days 3 to 28 was significantly higher ($P \leq 0.001$, $P=0.002$) for cattle treated with DRAXXIN than for those treated with Nuflor. In Study 1, first-treatment success for animals that received DRAXXIN was 73.7% compared with 30.3% for those that received Nuflor. In Study 2, first-treatment success for animals that received DRAXXIN was 82% compared with 64% for those that received Nuflor.

- Removals associated with BRD (chronics plus mortalities), in both studies, were lower for the group that received DRAXXIN than for the group that received Nuflor. In one study, the difference was significant ($P \leq 0.001$).

**INTRODUCTION**

DRAXXIN contains the active ingredient tulathromycin, the first of a subclass of macrolide, the triamilides, discovered and developed by Zoetis for use in livestock. DRAXXIN is a highly effective, single-dose antimicrobial medication indicated for treatment of BRD, and control of respiratory disease in cattle at high risk of developing BRD, caused by *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis*. DRAXXIN is formulated to have excellent syringeability, even at low temperatures, and a convenient low-volume dose (1 mL/40 kg; 1.1 mL/100 lb). When administered according to the label dose of 2.5 mg tulathromycin/kg body weight (BW), tulathromycin is rapidly absorbed, distributes widely (large apparent volume of distribution) and provides concentrations in bovine lung for an extended period. Clinical efficacy of DRAXXIN for treatment of BRD, as well as for control of respiratory disease in cattle at high risk of developing BRD, has been well documented in multiple feedlot and stocker studies.
Reported here are results of 2 studies that compared the efficacy of DRAXXIN with that of Nuflor for the treatment of undifferentiated BRD in cattle and their subsequent feedlot performance and carcass characteristics.

**Study 1**

**Materials and Methods**

In the spring of 2003, crossbred feeder steers (315 to 581 lb, 143 to 264 kg) purchased from auction markets in Minnesota, North Dakota, and Kansas, were transported to the study site in Nebraska, and processed (Figure 1). Processing at arrival included administration of BOVISHIELD™ 4, DECTOMAX® Injectable Solution, ULTRABAC® 7, and Ralgro® Implants. Animals were observed daily and those exhibiting clinical signs of BRD were examined further. Clinical attitude scores (CAS) were assigned as follows: 0 = normal, bright, alert, responsive; 1 = mild depression; 2 = moderate to marked depression (may be reluctant to stand); 3 = severe depression (unable to stand without assistance); 4 = moribund, unable to rise. Calves that had a CAS ≥1 and rectal temperature ≥104°F were selected by the investigator and randomly assigned, during 2 consecutive days, to receive treatment with a single dose of DRAXXIN (2.5 mg tulathromycin/kg BW) SC (n=100) or Nuflor (40 mg florfenicol/kg BW) SC (n=100). Day 0 was the day of enrollment and first treatment for each calf. Nasopharyngeal samples for bacterial isolation and identification were obtained from 20% of animals, randomly selected from each group, prior to treatment. Body weights for individual animals were recorded on day 0 (the day treatment was administered), if the animal required additional treatment, when an animal was removed from the study, day 28, at re-implanting on day 139 or 140, and at harvest on day 316 or 317.

From days 3 through 28, a CAS was recorded daily for each animal, and those fulfilling re-treatment criteria (CAS of 1 or 2 plus a rectal temperature ≥104°F, or a CAS of 3 or 4) received their 1st re treatment (LA-200®, 20 mg oxytetracycline/kg BW). Animals fulfilling these re-treatment criteria a second time received a 2nd retreatment (Baytril®, 11 mg enrofloxacin/kg BW). Re-treated animals were observed daily, but received no other treatment for 3 days following each re-treatment (with LA-200 or Baytril). From day 29 to close, animals that exhibited clinical signs of BRD (CAS of 1, 2, 3 or 4, regardless of rectal temperature) met re-treatment criteria. Animals that were re-treated 3 times during days 3 through 28 or 3 times between day 29 and close were classified as chronics and removed from the study. All remaining cattle were harvested on day 316 or 317, depending on the day of enrollment.

The study was conducted and analyzed according to the experimental design contained in the study protocol, which included random allocation of animals to groups, response data to be analyzed and statistical methods to be used.

**Results for Study 1**

First-treatment success\(^5\) for cattle treated with DRAXXIN was significantly higher (P≤0.001) than for cattle treated with Nuflor (days 3 through 28: DRAXXIN, 73.7%, Nuflor, 30.3%; days 29 through close: DRAXXIN, 53.2%, Nuflor, 23.2%; Table 1). Frequency distribution of 1st re-treatments during days 3 to 28 (Figure 2a) revealed daily numerical differences for animals in each treatment group. Cumulative distribution of 1st re-treatments during days 3 to 28 (Figure 2b) revealed marked differences among treatment groups when the day-to-day variability of the frequency distribution accumulated. Overall, fewer animals that received first treatment with DRAXXIN
required re-treatment than did those animals that received first treatment with Nuflor.
Removals due to BRD (chronics plus mortalities) were significantly lower (P≤0.001) for cattle treated with DRAXXIN than for cattle treated with Nuflor (days 3 through 28: DRAXXIN, 5.1%, Nuflor, 26.3%; days 3 through close: DRAXXIN, 20.2%, Nuflor, 47.5%; Table 1). During days 3 through close, 24 more cattle treated with Nuflor (42) were classified as chronics and removed from the study than those treated with DRAXXIN (18; Table 1). More cattle that were treated with Nuflor (5) died due to BRD than those treated with DRAXXIN (1; Table 1).
Average daily gain, calculated with mortalities and chronics removed, from days 0 through 28 was significantly higher (P=0.0001) for cattle treated with DRAXXIN (3.46 lb/day) than for cattle treated with Nuflor (2.40 lb/day). There was no significant difference (P=0.3877) for ADG from day 0 through close for the surviving cattle that received DRAXXIN or Nuflor (Table 2). There were no significant differences (P>0.05) for final live body weights, hot carcass weights (Table 3) or individual carcass variables (kidney/pelvic/heart fat, fat thickness, marbling score, ribeye area, carcass quality and yield grades recorded after an overnight chill).
Nasopharyngeal samples from 21 animals and pulmonary samples from 2 animals yielded P multocida, M haemolytica and H somni species with 9, 13, and 2 isolates, respectively. Samples from some animals yielded more than 1 organism.
No adverse product-related experiences were reported.

**Figure 1.** Experimental Design of Treatment Study 1 (Nebraska); DRAXXIN or Nuflor
Table 1. First-treatment and Re-treatment Successes for Treatment Study 1; DRAXXIN or Nuflor,* n (%)

<table>
<thead>
<tr>
<th>Success</th>
<th>Days 3-28</th>
<th>Days 3-Close**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DRAXXIN (n=100)</td>
<td>Nuflor (n=100)</td>
</tr>
<tr>
<td>First Treatment§</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st Re-treatment</td>
<td>13 (13.0%)</td>
<td>NA</td>
</tr>
<tr>
<td>2nd Re-treatment</td>
<td>8 (8.0%)</td>
<td>NA</td>
</tr>
<tr>
<td>3rd Re-treatment</td>
<td>0 (0.0%)</td>
<td>NA</td>
</tr>
<tr>
<td>4th Re-treatment</td>
<td>0 (0.0%)</td>
<td>NA</td>
</tr>
<tr>
<td>BRD Removals§</td>
<td>5 (5.1%)</td>
<td>26 (26.3%)</td>
</tr>
<tr>
<td>Chronic</td>
<td>5 (5.0%)</td>
<td>21 (21.0%)</td>
</tr>
<tr>
<td>BRD Mortalities</td>
<td>0 (0.0%)</td>
<td>5 (5.0%)</td>
</tr>
<tr>
<td>Non-BRD Removals §§</td>
<td>1 (1.0%)</td>
<td>1 (1.0%)</td>
</tr>
</tbody>
</table>

† NA = not analyzed.
* First Treatment = DRAXXIN or Nuflor
1st re-treatment = LA-200 (20 mg oxytetracycline/kg BW)
2nd re-treatment = Baytril (11 mg enrofloxacin/kg BW)
3rd re-treatment = standard feedlot treatment and animal removed from study
4th re-treatment = standard feedlot treatment and animal removed from study
Chronic = received ≥3 re-treatments and removed from study
Re-treatment Criteria
Days 3-28 - CAS of 1 or 2 and a rectal temperature of ≥104°F; or CAS of 3 or 4
Days >28 - CAS of ≥1
** Close was either day 316 or day 317 depending on day of enrollment.
§ BRD-associated mortalities and chronic. All percents calculated with number enrolled minus non-BRD removals as denominator.
 §§ Non-BRD removals included non-BRD associated mortalities.

Figure 2a. Frequency Distribution of Animals that Received Their 1st Re-treatment by Day, from Day 3 through Day 28; Treatment Study 1 (Nebraska); DRAXXIN or Nuflor

Figure 2b. Cumulative Distribution of Animals that Received Their 1st Re-treatment by Day, from Day 3 through Day 28; Treatment Study 1 (Nebraska); DRAXXIN or Nuflor
Table 2. Body Weight and Average Daily Gain for Animals that Remained in Treatment Study 1 (Nebraska); DRAXXIN or Nuflor

<table>
<thead>
<tr>
<th>Days</th>
<th>Initial Body Weight* (lb)</th>
<th>Final Body Weight (lb)</th>
<th>Average Daily Gain* (lb/day)</th>
<th>DRAXXIN P Value</th>
<th>Nuflor</th>
<th>DRAXXIN Nuflor</th>
<th>DRAXXIN P Value</th>
<th>Nuflor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-28</td>
<td>437.1</td>
<td>0.5306</td>
<td>441.8</td>
<td>534.1</td>
<td>509.0</td>
<td>3.46</td>
<td>0.0001</td>
<td>2.40</td>
</tr>
<tr>
<td>28-Re-implant**</td>
<td>534.1</td>
<td>0.0074</td>
<td>509.0</td>
<td>878.2</td>
<td>850.4</td>
<td>3.07</td>
<td>0.7836</td>
<td>3.05</td>
</tr>
<tr>
<td>Re-implant-Close†</td>
<td>878.2</td>
<td>0.0556</td>
<td>850.4</td>
<td>1417.2</td>
<td>1404.0</td>
<td>3.05</td>
<td>0.3772</td>
<td>3.13</td>
</tr>
<tr>
<td>0-Close</td>
<td>437.1</td>
<td>0.5446</td>
<td>441.8</td>
<td>1417.2</td>
<td>1404.0</td>
<td>3.09</td>
<td>0.3877</td>
<td>3.04</td>
</tr>
</tbody>
</table>

* Least-Squares Mean. Repeated measures mixed model least-squares mean estimates of body weight and average daily gain did not include values for animals removed before day 28, or for mortalities or chronics removed prior to the day of re-implant or the day of harvest.

Note: Mortalities and chronics removed.

** Re-implant occurred on day 139 or day 140.
† Close was day 316 or day 317 depending on day of enrollment.

Table 3. Carcass Adjusted Least-Squares Mean Final Body Weight, Weight Gain, Average Daily Gain and Hot Carcass Weight to Close* for Animals that Remained in Treatment Study 1 (Nebraska); DRAXXIN or Nuflor, n (SEM)

<table>
<thead>
<tr>
<th>Number of Animals</th>
<th>DRAXXIN</th>
<th>P Value</th>
<th>Nuflor</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Body Weight, lb</td>
<td>1378.0 (15.6)</td>
<td>0.8194</td>
<td>1372.4 (18.7)</td>
<td></td>
</tr>
<tr>
<td>Weight Gain, lb</td>
<td>937.8 (14.15)</td>
<td>0.7161</td>
<td>929.7 (16.99)</td>
<td></td>
</tr>
<tr>
<td>Average Daily Gain, lb/day</td>
<td>2.95 (0.04)</td>
<td>0.7161</td>
<td>2.93 (0.05)</td>
<td></td>
</tr>
<tr>
<td>Hot Carcass Weight, lb</td>
<td>895.7 (10.1)</td>
<td>0.8194</td>
<td>892.1 (12.2)</td>
<td></td>
</tr>
</tbody>
</table>

* Mortalities and chronics removed.

Study 2

Materials and Methods

Another study was performed in the spring of 2003 with feeder steers (348 to 692 lb, 158 to 314.5 kg) purchased from auction markets in Tennessee and transported to the study site in Colorado (Figure 3). Processing at arrival included administration of BOVISHIELD™ IBR/BVD, DECTOMAX, and Component® E-S Implant. Calves that had a CAS ≥ 1 and rectal temperature ≥ 104°F were selected by the investigator and randomly assigned, during 3 consecutive days, to receive treatment with a single dose of DRAXXIN (2.5 mg tulathromycin/kg BW) SC (n=100) or Nuflor (40 mg florfenicol/kg BW) SC (n=100). Animals from each treatment group (DRAXXIN or Nuflor) were commingled.

Cattle with a CAS of 1 or 2 plus a rectal temperature ≥ 104°F, or a CAS of 3 or 4, and that were at least 3 days post-treatment with DRAXXIN or Nuflor received their 1st re-treatment with ADVOCIN® (6 mg danofloxacin/kg BW), followed approximately 48 hours later by a second dose (6 mg danofloxacin/kg BW). Animals received no other treatment between the 2 doses of ADVOCIN. Animals fulfilling these re-treatment criteria a second time, and that were at least 2 days following the second dose of ADVOCIN, received their 2nd re-treatment.

Figure 3. Experimental Design of Treatment Study 2 (Colorado); DRAXXIN or Nuflor
Table 4. Treatment and Re-treatment Successes*: Field Study 2 (Colorado): DRAXXIN or Nuflor, n (%)

<table>
<thead>
<tr>
<th>Success</th>
<th>Days 3-28</th>
<th>Days 3-Close**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DRAXXIN (n=100)</td>
<td>Nuflor (n=100)</td>
</tr>
<tr>
<td>First Treatment§</td>
<td>82 (82%)</td>
<td>64 (64%)</td>
</tr>
<tr>
<td></td>
<td>0.002</td>
<td>0.009</td>
</tr>
<tr>
<td>1st Re-treatment</td>
<td>13 NA</td>
<td>23</td>
</tr>
<tr>
<td>2nd Re-treatment</td>
<td>2 NA</td>
<td>4</td>
</tr>
<tr>
<td>3rd Re-treatment</td>
<td>0 NA</td>
<td>0</td>
</tr>
<tr>
<td>4th Re-treatment</td>
<td>0 NA</td>
<td>0</td>
</tr>
<tr>
<td>BRD Removals§</td>
<td>3 (3%)</td>
<td>9 (9%)</td>
</tr>
<tr>
<td></td>
<td>0.058</td>
<td>0.058</td>
</tr>
<tr>
<td>Chronics</td>
<td>3 NA</td>
<td>9</td>
</tr>
<tr>
<td>BRD Mortalities</td>
<td>0 NA</td>
<td>0</td>
</tr>
<tr>
<td>Non-BRD Removals§§</td>
<td>0 NA</td>
<td>0</td>
</tr>
</tbody>
</table>

NA = not analyzed.

* First Treatment = DRAXXIN or Nuflor
1st re-treatment = A180 [2 doses, 6 mg danofloxacin/kg BW with approximately 48-hour interval]
2nd re-treatment = LA-200 [20 mg oxytetracycline/kg BW]
3rd re-treatment = standard feedlot treatment and animal removed from study
4th re-treatment = standard feedlot treatment and animal removed from study
Chronic = received ≥3 re-treatments and removed from study

Re-treatment Criteria
Days 3-28 and days 29 to close - CAS of 1 or 2 and a rectal temperature of ≥104°F; or CAS of 3 or 4

** Close was day 173 to 175 (mean = 173).
§ BRD-associated mortalities and chronics. All percents calculated with number enrolled minus non-BRD removals as denominator.
§§ Non-BRD removals included non-BRD associated mortalities.

Figure 4a. Frequency Distribution of Animals that Received Their 1st Re-treatment by Day, from Day 3 through Day 28; Treatment Study 2 (Colorado): DRAXXIN or Nuflor

Figure 4b. Cumulative Distribution of Animals that Received Their 1st Re-treatment by Day, from Day 3 through Day 28; Treatment Study 2 (Colorado): DRAXXIN or Nuflor
2nd re-treatment with LA-200 (20 mg oxytetracycline/kg BW). Animals that met these re-treatment criteria and were at least 2 days post-treatment with LA-200 were classified as chronics, and removed from the study. Re-treatment criteria and regimens were re-initiated on day 29. Animals that were re-treated 3 times during days 3 through 28 or 3 times between day 29 and close were classified as chronics and removed from the study. All animals remaining in the study were harvested on days 173 to 175.

**Results for Study 2**

First-treatment success for cattle treated with DRAXXIN was significantly higher (P=0.002 for days 0 through 28, and P=0.009 for days 0 through close) than that for cattle treated with Nuflor (days 0 to 28: DRAXXIN, 82% and Nuflor, 64%; days 3 through close: DRAXXIN, 79.4% and Nuflor, 63.6%; Table 4). The frequency distribution of 1st re-treatments during days 3 to 28 (Figure 4a) revealed daily numerical differences for animals treated in each treatment group. Cumulative distribution of 1st re-treatments during days 3 to 28 (Figure 4b) revealed marked differences between treatment groups when the day-to-day variability of the frequency distribution accumulated. Overall, fewer animals that received first treatment with DRAXXIN required re-treatment than did those animals that received Nuflor. Removals due to BRD were not significantly different (P=0.058) for either treatment group during days 0 through 28, and for days 0 through close. The ADG was not significantly different for days 0 through 28 (P=0.7152), days 28 through day of re-implanting (P=0.7931), or days 0 through close (P=0.1113) for cattle in either treatment group (Table 5). There were no significant differences (P>0.05) for final live body weights, hot carcass weights (Table 6) or individual carcass variables (kidney/pelvic/heart fat, fat thickness,
marbling score, carcass quality and yield grades after an overnight chill). Ribeye area for cattle treated with DRAXXIN (13.98 in²) was significantly larger (P=0.0396) than that for cattle treated with Nuflor (13.50 in²).

No adverse product-related experiences were reported.

Discussion

Bacteria isolated from clinically affected cattle prior to initial treatment during this study were consistent with those associated with BRD. DRAXXIN is approved for treatment and control of BRD caused by *M. haemolytica, H. somni, P. multocida* and *Mycoplasma bovis*.

DRAXXIN was more efficacious than was Nuflor, based on response to first treatment in both studies reported here. The substantial response to first treatment with DRAXXIN was followed by fewer re-treatments than for cattle that received Nuflor. That finding, in light of the different medications used for 1st and 2nd re-treatment, suggests that the choice of medication for first treatment had a major influence on response to subsequent treatment. Frequency distribution and cumulative distribution for 1st re-treatments should be considered when evaluating clinical response to treatment against BRD because they provide excellent, though different, views of the same information.

The number of BRD-associated removals (mortalities and chronics) was significantly (P<0.05) different for the 2 treatment groups in Study 1. In Study 2, the difference of BRD-associated removals for the 2 treatment groups was not significant at P=0.05 but was at P=0.058. That latter P value indicates that there was a 94.2% probability that the difference in BRD removals found in Study 2 was actually attributable to DRAXXIN. Re-treatment criteria were consistent within each phase of these studies, but were different in the first phase (days 3 through 28) from those in the second phase (days 29 through close). As a result, a few animals were re-treated more than 3 times, throughout the course of the study, before they were classified as chronics and removed from the study. In 1 of the 2 studies reported here, ADG for animals that remained in the studies was greater for those treated with DRAXXIN than for those treated with Nuflor.

In order to minimize confounding influences on results, animals were randomly assigned to receive one of the respective medications being evaluated. Management practices and processing at each site of investigation were consistent for all animals within a given study. Recording of the disposition of animals removed from the studies (BRD-associated or non-BRD associated removals) was not included in the protocol; therefore, that information is not available for analysis or discussion. Before each study began, regimens for administration of those medications as well as subsequent medication (if needed) were stated in the respective protocols. Criteria for administration of subsequent medication and for classifying the responses were also defined to be consistent within the study. Because those steps were implemented, results within a given study could be attributed to the respective medication being evaluated.
Conclusion
Results of these treatment studies provide evidence that DRAXXIN administered as a single SC injection was safe and significantly more effective than was Nuflor for the treatment of undifferentiated BRD in cattle used in these studies. In both studies, DRAXXIN resulted in greater first-treatment success and lower BRD-associated removals (mortalities and chronics).

IMPORTANT SAFETY INFORMATION:
DRAXXIN has a pre-slaughter withdrawal time of 18 days. Do not use in female dairy cattle 20 months of age or older. Do not use in animals known to be hypersensitive to the product. See full Prescribing Information.

References
5  First-treatment success = did not meet criteria for subsequent treatment, referred to as retreatment.
6  Chronic = received ≥3 re-treatments and removed from study.
Adverse Reactions

Cattle

In one BRD field study, two calves treated with DRAXXIN at 2.5 mg/kg BW exhibited transient hypertransaminasemia. One of these calves also exhibited transient dyspnea, which may have been related to pneumonia.

Post Approval Experience

The following adverse events are based on post approval adverse drug experience reporting. Not all adverse events are reported to the FDA CVM. It is not always possible to reliably estimate the frequency of occurrence or establish a causal relationship to product use by these data sources. The following adverse events are listed in descending order of their frequency of reporting frequency: ocular, gastrointestinal, dermatological, and neurological/adynamical reactions. For a complete listing of adverse reactions for DRAXXIN Injectable Solution see the reported CVM at: http://www.fda.gov/vets/adverseeffect.

Clinical Pharmacology

At pharmacological doses (a week's dose) is approximately 50 times more soluble in hydrophilic media than in hydrophobic media. This solubility profile is consistent with the extracellular pathogen activity typically associated with the macrolides.1 Macrolide antibiotics, including DRAXXIN, are generally larger than the size of the plasma proteins to which they bind and are larger than the plasma proteins compared to the plasma. The extent to which long plasma concentrations represent free (PAE) macrolides tend to be primarily bactericidal, but may be bacterialized against some pathogens2 They also tend to exhibit concentration-dependent killing, the rate of which is dependent on whether or not a serum concentration drug concentrations reach 2 to 3 times the minimum inhibitory concentration (MIC) of the targeted pathogens. Under these conditions, the time that serum concentrations remain above the MIC becomes the major determinant of antimicrobial action. Macrolides also exhibit a post-antimicrobial effect (PAE), the duration of which tends to vary with both drug and pathogen dependent. In general, by increasing the macrolide concentration and the exposure time, the PAE will increase to a more substantial duration. Of the two variables, concentration and exposure time, drug concentration tends to be the most powerful determinant of the duration of the PAE. T tulathromycin is eliminated from the body primarily unchanged via an biliary excretion.1 2


Calf

Following subcutaneous administration into the neck of feeder calves at a dosage of 2.5 mg/kg BW, tulathromycin is rapidly and nearly completely absorbed. Peak plasma concentrations generally occur within 15 minutes after dosing and predict relative bioavailability exceeds 90%. Total systemic clearance is approximately 170 mL/h/kg. Tulathromycin distributes extensively into body tissues, as evidenced by volume of distribution values of approximately 11.9 L/kg for healthy broilers.1 This extensive volume of distribution is largely responsible for the long elimination half-life of this compound (approximately 2.7 days in the plasma (based on quantitation terminal plasma drug concentrations) versus 8.75 days for total administration of the drug to animals). Linear pharmacokinetics are observed with subcutaneous doses ranging from 1.25 mg/kg BW to 3.75 mg/kg BW. No pharmacokinetic differences are observed in castrated males versus female calves.3,4

Concentration and volume of evidence are based on intersubject comparisons of 2.5 mg/kg BW administration by subcutaneous or intravenous injection.

Microbiology

Cattle

Tulathromycin has demonstrated in vitro activity against Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, Porphyromonas levii, and Moraxella bovis associated with BRD against: Mannheimia haemolytica and Pasteurella multocida and Agrobacterium on bovine foot rot.

The MICs of tulathromycin against indicated BRD and IBK pathogens were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLSI, 2007-2017) and 4 Methods for Determining the Minimum Inhibitory Concentration (MIC) of Antimicrobial Agents for Anaplasma phagocytophilum and Ehrlichia chaffeensis.1,2

Mouse

Foot Rot - The effectiveness of DRAXXIN for the treatment of bovine foot rot was evaluated in 170 cattle in two field studies. Cattle diagnosed with bovine foot rot were enrolled and treated with a single subcutaneous dose of 2.5 mg/kg BW or an equivalent volume of saline. Cattle were clinically evaluated 7 days after treatment for treatment success, which was based on defined decreases in lesion, swelling, and lameness scores. In both studies, the treatment success percentage was statistically significantly higher in DRAXXIN-treated calves compared with saline-treated calves (60% vs. 8%, P < 0.0001 and 83.3% vs. 50%, P = 0.0088).1

Animal Safety

Cattle

Safety studies were conducted in feeder calves receiving a single subcutaneous dosage of 25 mg/kg BW or 3 weekly subcutaneous dosages of 25, 7.5, or 12.5 mg/kg BW at 7, 10, and 13 days of age. Calves were treated intramuscularly with field strains of Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, Moraxella bovis and Agrobacterium on bovine foot rot. Microbiologically, minimal to mild myocardial degeneration was seen in one of six calves administered 12.5 mg/kg BW or an equivalent volume of saline. Cattle were clinically evaluated 7 days after treatment for treatment success, which was based on defined decreases in lesion, swelling, and lameness scores. In both studies, the treatment success percentage was statistically significantly higher in DRAXXIN-treated calves compared with saline-treated calves (8% vs. 6%, P = 0.0032 and 83.5% vs. 50%, P = 0.0088).

Storage Conditions

DRAXXIN Injectable Solution is available in the following package sizes: 50 mL, 100 mL, 250 mL, and 500 mL. The combination of the antibiotic with its diluent is stable for at least 2 years when stored at controlled room temperature (5°C to 30°C) or in refrigerated conditions (2°C to 8°C). For additional data requirements for handling and administration, see the package insert. Zoetis recommends the use of a well-mixed suspension before administration and the use of a syringe with at least a 16 gauge bore diameter to ensure adequate drug delivery.

Now-supplied Product

For the now-supplied product, refer to the bottom of the page for a link to more information.