Metaphylactic Use of DRAXXIN® (tulathromycin) in Weaned Dairy Calves at High Risk for Infectious Respiratory Disease

Zoetis Inc.
Madison, NJ 07940

Summary

- Metaphylactic antimicrobial treatment of weaned dairy calves immediately prior to movement from individual to group housing offers an opportunity to prevent bovine respiratory disease (BRD) in these high-risk animals.
- The efficacy of DRAXXIN® metaphylaxis in high-risk dairy calves was evaluated in 6 controlled research trials conducted in different regions of the US.
- A single metaphylactic dose of DRAXXIN yielded favorable outcomes for all health and performance parameters evaluated in the studies (compared to non-treated controls).
  - BRD incidence was significantly reduced ($P \leq 0.0162$) by 27% to 73% in 4 of the studies, while pinkeye incidence (a collateral observation) was completely avoided ($P \leq 0.0002$) at a dairy where 12.5% of control animals experienced illness.
  - As a result of excellent disease control, average daily gain was significantly improved ($P \leq 0.0395$) by 4.1% to 22% in 3 studies.
  - Economic analyses performed in 3 studies demonstrated net financial benefits up to $17/head as a result of DRAXXIN metaphylaxis.
- Metaphylactic administration of DRAXXIN to dairy calves at the time of movement to group housing reduces disease incidence and positively influences the productivity potential of replacement heifers and dairy-beef steers.

Bovine respiratory disease (BRD) is the leading cause of mortality in weaned dairy calves, while disease prevalence has changed little from the 1990s.1,2 Dairy calves are at particularly high risk of BRD because movement shortly after weaning from individual hutches to group housing imposes unavoidable stressors (environmental, transportation, nutritional, social) that can suppress the immune system. Furthermore, this immunosuppression often coincides with a period of increased risk of exposure to respiratory pathogens.

Metaphylactic medication of cattle at high risk of BRD (before clinical symptoms appear) has become widely used for preventing disease in newly arrived feedlot cattle.2 Although metaphylaxis is less widely practiced in dairy operations, use is increasing for weaned calves immediately prior to movement from individual to group housing. Metaphylaxis offers the advantage of preventing BRD or treating subclinical infection before the...
appearance of clinical disease which erodes performance and demands therapeutic treatment. The benefits of metaphylaxis for dairy calves may be even greater than the benefits observed for feeder or stocker cattle since commingling of the younger, smaller dairy heifers increases the risk of BRD earlier in the production cycle. Furthermore, smaller animals require less medication, so economic returns associated with a dairy-calf metaphylaxis program may be improved relative to those for stocker/feeder cattle.

**DRAXXIN®**

DRAXXIN (tulathromycin) Injectable Solution is the unique, novel BRD treatment that conveniently delivers a full course of therapy in a single dose. Tulathromycin is a semi-synthetic macrolide compound developed by Zoetis scientists as a highly bioavailable, long-acting antimicrobial for treatment of BRD. Administered as a single subcutaneous (SC) injection at 1.1 mL/100 lb body weight (2.5 mg/kg), DRAXXIN is indicated for treatment of BRD associated with 4 of the most common bacterial respiratory pathogens of cattle: *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*. DRAXXIN is also the only BRD product approved for the control of respiratory disease in cattle at high risk of developing BRD associated with the same 4 pathogens. These indications make DRAXXIN particularly well-suited for use in metaphylaxis programs for dairy calves, when animals experiencing stress due to weaning, transport, commingling, etc., are at high risk of BRD pathogen exposure. In addition, DRAXXIN is also indicated for the treatment of infectious bovine keratoconjunctivitis (IBK, or pinkeye) associated with *Moraxella bovis*, and for the treatment of bovine foot rot (interdigital necrobacillosis).

**Metaphylaxis Research**

The efficacy of DRAXXIN metaphylaxis in high-risk dairy calves was evaluated in 6 controlled research trials conducted in different regions of the US. Large commercial Holstein dairies or calf-rearing operations with recent histories of clinical BRD were selected for the studies. At each site, clinically normal weaned heifer or steer calves were enrolled in groups as they became available from the herd, at the time of relocation from individual hutches to group pens. Calves were randomly allocated to either of 2 treatment groups in approximately equal numbers:

- Control (non-treated);
- DRAXXIN: single SC injection, 1.1 mL/100 lb body weight.

Average daily gain (ADG) and disease morbidity (calves displaying clinical signs of respiratory disease) were assessed during each trial, but other design details varied by study.

**Study A**

**Experiment Design**

A 5000-cow dairy located in Texas was the location for the first study. About 80 heifer calves were enrolled in the study each week over a 3-week period (240 total). At 60 days of age, the Holstein calves were weighed, assigned to treatment groups, treated, and commingled in a group pen. Total enrollment was 118 for the DRAXXIN group and 119 for the control group. Cattle were weighed again 28 days later (study conclusion) and ADG was calculated on a deads-out basis (1 animal). Rates of BRD incidence were recorded, and calves that developed BRD were treated with an antimicrobial other than DRAXXIN. Calves in the DRAXXIN metaphylaxis group were not retreated if BRD developed during the first 7 days of the study period (post-metaphylaxis interval).

**Results**

Initial body weights of calves were similar for both treatment groups. Study results summarized in Figure 1 show that calves in the DRAXXIN metaphylaxis group generated a dramatic 0.38-lb (22.4%) increase ($P \leq 0.0001$) in ADG compared to the control group. This ADG improvement provided a mean weight-gain advantage of 10.7 lb/head for metaphylaxis vs control calves during the 28-day trial.

The highly favorable performance outcomes for DRAXXIN-medicated calves were the result of a significantly lower ($P \leq 0.0005$) incidence of BRD in that group (9.3%) compared to controls (34.5%). Thus, as a result of metaphylaxis,

**Important Safety Information:** Do not use DRAXXIN in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. DRAXXIN has an 18 day pre-slaughter withdrawal.
more than 25% of the calves in the DRAXXIN group were spared from developing clinical BRD; or in other words, for every 4 calves treated with DRAXXIN, 1 case of BRD was avoided. Calves treated with DRAXXIN also required 72% fewer (\(P \leq 0.0001\)) BRD treatments per calf compared to controls.

**Study B**

*Experiment Design*

The second study was conducted at a 3000-cow dairy in Ohio where 3 groups of 68 calves each were enrolled on a biweekly cycle. The 204 Holstein heifers, 65 to 75 days of age, were weighed, assigned to treatment groups, treated, and commingled in a group pen. Total enrollment was 102 for each treatment group. Cattle were weighed again 17 to 25 days after treatment (study conclusion) depending on the group in which they were enrolled. Non-treated control calves that developed BRD during the first 7 days received treatment with florfenicol. After day 7 of the study, all calves were eligible for treatment as needed (florfenicol). Treatment costs were determined by group and calculated on a per-head basis using $0.50/mL for antimicrobial cost, $0.20/mL for the cost of nonsteroidal anti-inflammatory drugs (NSAID), and $1.00 per treatment for labor.

**Results**

Study results summarized in Figure 2 show that calves in the DRAXXIN metaphylaxis group gained 0.17 lb (6.5%) more per day (\(P = 0.1534\)) than the control group (initial calf weights similar between groups). The BRD threat was quite high in this study, evidenced by a BRD morbidity rate of >80% in control animals, but no mortality occurred. Compared to controls, calves that received DRAXXIN metaphylaxis experienced 58.4% less (\(P \leq 0.0001\)) BRD morbidity and a 63.8% reduction (\(P \leq 0.0001\)) in the rate of first pulls for BRD treatment. Consistent with these results, the average cost of clinical BRD treatment was significantly reduced (\(P \leq 0.0001\)) in the DRAXXIN metaphylaxis group by $1.87/head (59.6%) relative to controls.
Study C

Experiment Design
A 4000-cow New Mexico dairy was used for the Study C, with 4 groups of approximately 50 calves each enrolled on a biweekly cycle (200 total). At 70 days of age, heifers were weighed (167 lb average), randomly assigned to treatment groups, treated, and commingled in a group pen. A total of 104 healthy calves were enrolled in the DRAXXIN-treated group and 101 healthy calves were assigned to the control group. Cattle were weighed again 28 to 43 days after treatment (study conclusion) depending on the group in which they were enrolled. Though ADG was the principal intended parameter for evaluation at this dairy (BRD not recorded), an outbreak of severe IBK in some control calves prompted the inclusion of IBK incidence as an additional outcome measure. Since all animals experienced a dry, dusty, windy environment plus a natural IBK challenge equally distributed among all calves, no bias was considered to have occurred.

Results
Calves that received DRAXXIN metaphylaxis grew 0.17 lb/day faster than animals in the control group (Figure 3), a significant 10.9% improvement (P ≤ 0.03). Thus, DRAXXIN-medicated calves gained 4.8 to 7.3 lb more weight than control animals during the 28- to 43-day trial period.

As a collateral observation in the study, clinical signs of pinkeye were observed in 12.5% of control calves during the study, but no cases of pinkeye occurred in the DRAXXIN group (100% reduction, P ≤ 0.0002). Thus, for every 8 calves treated with DRAXXIN, 1 case of pinkeye was avoided.

Even though BRD incidence was low in Study D, net financial returns still improved by nearly $10/hd in the DRAXXIN® group.

Study D

Experiment Design
A fourth study involved a predominately Holstein dairy located in Michigan that enrolled 234 calves enrolled over a 6-week period. Each week, a cohort of calves was weaned at 56 days of age, and later the animals were commingled and transported to a grower facility for a 10-week grower period. Upon arrival, calves were weighed (average 214 lb, 77 days of age), randomly assigned to treatment groups, treated, and commingled in group housing, with each week’s enrollment constituting a replicate. Total enrollment was 115 for the DRAXXIN group and 119 for the control group. Group weights were obtained 73 days later (study conclusion, approximately 150 days of age) and ADG was calculated on a deads-out basis. Rates of BRD incidence were recorded and calves that developed BRD were treated with enrofloxacin for the first and second pulls, and florfenicol for third pulls. Calves in the DRAXXIN metaphylaxis group were not eligible for BRD treatment during the first 7 days of the study period. An economic analysis was performed for this study and included values for metaphylaxis cost ($8.53/hd), weight gain ($1.50/lb), and BRD treatment costs (medications + labor at $10/hour).

Results
BRD incidence and severity was low in this study as only 4.2% of control calves and 1.7% of DRAXXIN calves required treatment for BRD, with 1 mortality recorded for each treatment group. Still, calves that received DRAXXIN metaphylaxis generated 5.6% better ADG than controls (P = 0.0781, Figure 4). Therapeutic treatment costs for control calves
Results

Study results summarized in Figure 5 show that calves in the DRAXXIN metaphylaxis group gained 4.1% (0.10 lb) more per day ($P = 0.0395$) than control calves, or 8.0 lb/head more than controls during the 85-days on test. The BRD threat was high in this study, evidenced by 46.8% of control animals requiring at least 1 treatment for BRD, and 2 mortalities due to BRD. In contrast, only 34.0% of DRAXXIN calves needed BRD treatment (no deaths), so DRAXXIN metaphylaxis reduced the incidence of first pulls for BRD treatment by 27.4% ($P = 0.0162$). Furthermore, the BRD therapeutic treatment rate (total treatments ÷ total animals) was nearly cut in half by DRAXXIN metaphylaxis (53.5%, $P = 0.0003$) compared to controls (100.8%), and the rate of BRD chronics (≥ 3 treatments) was only 4.9% in DRAXXIN animals compared to 17.7% for controls ($P = 0.0002$). As a result, therapeutic BRD treatment costs for control calves averaged $10.67/head vs $6.04/head for calves receiving DRAXXIN ($P = 0.0007$). After considering all costs associated with metaphylaxis, BRD treatment, mortalities, and the value of weight gains, overall economic returns favored the DRAXXIN group by an average of $17.01/head. Thus, the 167 DRAXXIN metaphylaxis calves enrolled in this study returned approximately $2840 more income than the pull-and-treat control animals.

The fact that animals were individually weighed in this study provided an opportunity to quantify weight gains relative to the number of needed BRD treatments (Figure 6). ADG was consistently eroded as the number of needed BRD treatments increased (indicative of increasing BRD severity/persistence). At the averaged $0.77/head while costs for DRAXXIN-treated calves averaged only $0.31/head. After all medication costs, the overall economic returns for control calves averaged $292.48/head compared to $302.41 for calves in the DRAXXIN group. Thus, an overall average benefit of $9.93/head was realized for calves that received DRAXXIN metaphylaxis after accounting for the cost of the metaphylactic treatment, even though BRD incidence and severity was low.

Study E

Experiment Design

An Indiana dairy-steer grower facility with a capacity of 850 animals was the location for Study E. For this study, the operation received 334 Holstein bull calves after they were housed in hutches for 7 weeks at a calf-hutch facility. Upon arrival, calves ranged from 68 to 76 days of age and were randomly assigned to treatment groups, individually weighed, treated, and commingled in group housing. Total enrollment was 167 for each treatment group (DRAXXIN metaphylaxis and controls). Individual weights were obtained again 85 days later (study conclusion) and ADG was calculated on a deads-out basis. Rates of BRD incidence were recorded and calves that developed BRD were treated with enrofloxacin for the first and second pulls, and florfenicol for third pulls, observing a 3-day post-treatment interval for all treatments. Calves in the DRAXXIN metaphylaxis group were not eligible for BRD treatment during the first 10 days of the study. An economic analysis was performed that included values for metaphylaxis cost ($8.29/hd), weight gain ($1.50/lb), mortality ($588/hd), and costs associated with BRD treatment.
extremes, calves that remained clinically healthy grew 0.53 lb/day more than chronic calves that received 3 or more therapeutic treatments for BRD. These outcomes illustrate the rationale for DRAXXIN metaphylaxis which helped dramatically reduce the number of BRD treatments required during the 85-day study and yielded a net financial benefit of $17/head.

Study F

Experiment Design

The final study was conducted at a California dairy, with 6 groups of 80 heifer calves raised in hutches enrolled over a 4-week period (480 total). At approximately 72 days of age, each group of calves were group-weighed (average 185 lb/hd), transferred to a grower facility, randomly assigned to treatment groups (40/group), treated, and commingled in an open-lot pen. Thus, a total of 240 healthy calves were enrolled in each of the DRAXXIN and control groups. Cattle were weighed again approximately 68 days after treatment (study conclusion) and ADG was calculated on a deads-out basis. Rates of BRD incidence were recorded and calves that developed BRD were treated with florfenicol for all pulls (3 mL/hd intravenously, extra-label dosing by dairy staff). Calves in the DRAXXIN metaphylaxis group were not eligible for BRD treatment during the first 10 days of the study. An economic analysis was performed for this study and included values for metaphylaxis cost ($6.82/hd), weight gain ($1.50/lb), mortality ($494/hd), and BRD treatment costs (medication + labor at $10/hour).

Upon study completion, a random subsample of approximately 18% of calves from each treatment group (42 DRAXXIN, 43 control) were examined by ultrasound to determine the incidence and severity of lung lesions. Calves were scored using a numerical scale ranging from 1 to 4 (1 = no lesions, 4 = severe lesions).

Results

BRD incidence and severity was moderate in this study, with 26.7% of control calves requiring treatment for BRD (Figure 7) and 1 mortality. In contrast, only 12.9% of DRAXXIN calves were pulled for BRD (with no deaths), a 51.7% reduction ($P = 0.0138) compared to the control group. Similarly, the BRD therapeutic treatment rate (total treatments ÷ total animals) was dramatically reduced by 54.4% in the DRAXXIN group compared to controls ($P = 0.0053). Growth performance was best for calves that received DRAXXIN metaphylaxis, with ADG of 2.20 lb vs 2.12 lb for controls. Though this 3.8% improvement in ADG for DRAXXIN calves was substantial, it was not statistically significant due to the low number of data values (6/group) as a result of using group weights instead of individual weights in this trial. The economic analysis of study results revealed that DRAXXIN metaphylaxis generated a net average benefit of $4.23/head even though therapeutic BRD treatments were not administered according to label directions and the magnitude of the favorable growth response was not as great as that observed in other studies.

The random subsamples of calves used for assessment of lung lesions were deemed...
perhaps including viral agents. Under these severe disease conditions, DRAXXIN metaphylaxis reduced BRD incidence 58.4%. This outcome indicates that though high rates of BRD can still occur in calves treated metaphylactically, non-treatment invites even higher rates of disease in high-risk calves, especially in herds with a recent history of BRD. A high rate of BRD, even in treated calves, is not surprising given the wide variety of bacterial and viral pathogens involved and multiple stressors that can potentially affect dairy calves.

In Study C, DRAXXIN-treated calves completely avoided the outbreak of IBK (pinkeye), a known source of production losses in cattle10 (DRAXXIN does not have a claim for control of IBK). ADG was significantly improved in the DRAXXIN group compared to controls, perhaps reflecting the adverse impact of pinkeye on feeding efficiency and the favorable effects of avoiding pinkeye.

DRAXXIN metaphylaxis clearly reduced evidence of lung damage attributed to bacterial respiratory disease during the course of Study F. The lungs of 90.7% of examined calves that received DRAXXIN metaphylaxis were free of lung lesions at 68 days post-treatment compared to only 45.1% of examined control calves. Thus, approximately 55% of the control calves examined were found to harbor detectable lung lesions of various severities, compared to only 9.5% of the examined DRAXXIN-treated calves (all ‘mild’ lesions).

Implications
These 6 studies provide compelling evidence that a single metaphylactic dose of DRAXXIN administered to high-risk dairy calves can help significantly reduce BRD incidence, reduce the frequency and costs of BRD treatments, avoid ADG degradation associated with disease, and yield net financial benefits. Because consistent reductions of clinical disease were accomplished in geographically diverse production settings involving nearly 1700 newly weaned calves, the studies offer a strong database in support of metaphylaxis.

Study A demonstrated a 73% reduction in BRD morbidity as a result of DRAXXIN treatment, under conditions where disease incidence in controls was 34.5%. In contrast, BRD occurred in 80.3% of controls in Study B, indicative of an active outbreak or endemic exposure.

Economic analyses performed in 3 studies (including therapeutic and metaphylactic treatment costs, labor, ADG, and mortalities) demonstrated net financial benefits up to $17/head as a result of DRAXXIN metaphylaxis. However, a true cost-effectiveness analysis would need to include feed costs, which was beyond the scope of these studies. Notably, DRAXXIN-treated calves in 3 of the studies demonstrated significant improvements in ADG (and ADG of treated calves in the other studies was numerically improved but not statistically significant). The rationale for these growth improvements is that metaphylactic treatment helps reduce BRD incidence and thus helps avoid the depression in feed intake that is typically associated with clinical illness. Furthermore, the average cost of treating BRD in Study B (no economic analysis performed) was reduced 59.6% in DRAXXIN-treated calves compared to controls.

Figure 8 – Study F. Impact of metaphylactic DRAXXIN treatment on lung lesion incidence and severity.

Impacts of metaphylactic treatment on lung lesion scores. 90.7% of DRAXXIN® calves were free of lung lesions vs only 45.1% of controls.
vs controls, and the percentage of first pulls for treatment was reduced 63.8%, highly significant outcomes that clearly help justify the cost of metaphylactic treatment.

The adverse effects of BRD on weight gain are sometimes overlooked in dairy settings, where replacement heifer calves are not raised for beef production. However, research has identified ADG as a surrogate marker for the impact of respiratory disease in dairy animals.\(^2\)\(^{11}\) Optimum weight gain is not only correlated with a lower risk of BRD, but it also allows dairy calves to reach breeding weight and height sooner and realize improved conception rates. Similarly, IBK is a high-morbidity disease that can cause severe clinical signs and markedly reduce productivity.\(^12\) Thus, prevention of these common infectious diseases of cattle by metaphylactic antimicrobial treatment is often reflected by improved weight gain, as demonstrated in these studies.

**Conclusions**

A single metaphylactic dose of DRAXXIN administered to weaned dairy calves prior to movement to a high-risk, post-weaning environment significantly lowered the incidence of BRD and improved weight gains. Both the frequency and cost of BRD treatments were correspondingly reduced as a result of lower incidence of BRD in DRAXXIN-treated calves, and net financial benefits beyond the cost of metaphylaxis were demonstrated in studies that included economic analyses.

Metaphylactic use of DRAXXIN represents a sound management strategy that allows dairy producers to reduce disease incidence and positively influence the productivity potential of replacement heifers and dairy-beef steers.

**Important Safety Information:** Do not use DRAXXIN in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. DRAXXIN has an 18 day pre-slaughter withdrawal
References
5. Data on file, Study Report No. 09PETDRA03, Zoetis Inc.
6. Data on file, Study Report No. 08PETDRA01, Zoetis Inc.
Antibiotic

100 mg of talithromycin/mL

For subcutaneous injection in beef and nonabated dairy cattle and intramuscular injection in other species. Use Draxxin® daily calves 28 months of age or older in calves to be processed for beef.

CAUTION

The following restrictions and a description of dietary replacement are not intended to replace professional advice but are intended to provide useful information to veterinarians and producers.

DESCRIPTION

Draxxin® Injectable Solution is a ready-to-use sterile parenteral preparation containing talithromycin, a semisynthetic macrolide antibiotic of the macrolide lactam, each mL of Draxxin® contains 100 mg of talithromycin as the base in 20% propylene glycol, monomethylol (5%), with cortisone acetate and triamcinolone acetonide added to 1%.

Draxxin® consists of a well-characterized mixture of two isoforms of talithromycin in a 1:1 ratio. Structures of the isomers are shown below.

Table 1: Draxxin® Cattle Dosage Guide

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<th>Animal Weight (Pounds)</th>
<th>Drug Volume (mL)</th>
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Table 2: Draxxin® Steer Dosage Guide

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CONTRAINDICATIONS

The use of Draxxin® Injectable Solution is contraindicated in animals previously known to be hypersensitive to this product or any component of this product.

WARNINGS

DO NOT USE IN ANIMALS ONLY FOR USE IN ANIMALS NOT FOR USE IN CHILDREN OR TURKEYS.

Table 3: Draxxin® Minimum Inhibition Concentration (MIC) Values

<table>
<thead>
<tr>
<th>Indicated Pathogen</th>
<th>MIC Range (μg/mL)</th>
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<tr>
<td>Agrobacterium tumefaciens</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Bacillus subtilis</td>
<td>1.0</td>
</tr>
<tr>
<td>Bacteroides fragilis</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Campylobacter jejuni</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>0.25 to 100</td>
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<tr>
<td>Enterococcus faecalis</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Klebsiella pneumoniae</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Pasteurella multocida</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Salmonella choleraesuis</td>
<td>0.25 to 4</td>
</tr>
<tr>
<td>Salmonella enterica</td>
<td>0.25 to 4</td>
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The dosage volume is 5 mL for both cattle and the frequency of dosing is once daily for 10 days.