Successfully navigating The Vital 90™ Days is reason to celebrate. It means you’ve managed both immune suppression and negative energy balance during an extremely vulnerable time. Your cows have avoided diseases like mastitis, metritis, retained placenta, displaced abomasum, ketosis, and ovarian dysfunction. And you’ve set your herd up for success during the peak phase of the lactation cycle.

Contact your veterinarian or Elanco representative for more information about The Vital 90 Days, and how you and your herd management team can depend on Elanco, when your cows depend on you most. Cheers!


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A Comparative Study on the Efficacy of Titanium 3 vs. Pyramid® 2 + Type II BVD in the Prevention of Bovine Respiratory Disease

Objective

This study was conducted to evaluate:
- The effectiveness of Titanium® 3 administered on arrival compared to Pyramid® 2 + Type II BVD vaccine, in reducing the morbidity and mortality due to naturally occurring bovine respiratory disease
- The performance of calves administered Titanium 3 or Pyramid 2 + Type II BVD

Study design

- Included 5,000 medium risk backgrounded steers (4 reps) and heifers (6 reps) approximately 12 months of age
- Cattle were assigned randomly to two treatment groups: Titanium 3 or Pyramid 2 + Type II BVD
- Cattle received Micotil® (tilmicosin injection) metaphylaxis at 1.5 mL/100 lbs
- Body weights were measured at allocation (treatment assignment) and at terminal weight sort
- Ear notch samples were taken from every animal at allocation and stored frozen
- Feed intake was recorded by pen
- Weight gain, ADG, DDMI, F/G and health data (morbidity and mortality) were analyzed at study end

Results

Table 1. Health data

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<th>Titanium 3</th>
<th>Pyramid 2 + Type II BVD</th>
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<td>BRD - 4th pulls, %</td>
<td>28.7</td>
<td>10.0</td>
<td>6.86</td>
<td>0.09</td>
</tr>
<tr>
<td>Chronic BRD, %</td>
<td>0.64</td>
<td>0.44</td>
<td>0.23</td>
<td>0.56</td>
</tr>
<tr>
<td>Arthritis, %</td>
<td>0.60</td>
<td>0.60</td>
<td>0.11</td>
<td>1.00</td>
</tr>
<tr>
<td>Mortality, %</td>
<td>1.24</td>
<td>1.04</td>
<td>0.22</td>
<td>0.55</td>
</tr>
<tr>
<td>BRDHS* Mortality, %</td>
<td>0.56</td>
<td>0.56</td>
<td>0.18</td>
<td>1.00</td>
</tr>
</tbody>
</table>

*Bovine Respiratory Disease and Histophilus somnus

Table 2. Performance

<table>
<thead>
<tr>
<th></th>
<th>Titanium 3</th>
<th>Pyramid 2 + Type II BVD</th>
<th>SE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. pens</td>
<td>10</td>
<td>10</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>No. head</td>
<td>2,500</td>
<td>2,500</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Average in-weight, lbs</td>
<td>785</td>
<td>783</td>
<td>0.88</td>
<td>0.14</td>
</tr>
<tr>
<td>Average terminal weight*, lbs</td>
<td>1,212</td>
<td>1,220</td>
<td>3.73</td>
<td>0.16</td>
</tr>
<tr>
<td>Average weight gain, lbs</td>
<td>426</td>
<td>436</td>
<td>4.01</td>
<td>0.11</td>
</tr>
<tr>
<td>ADG, lbs</td>
<td>3.33</td>
<td>3.44</td>
<td>0.05</td>
<td>0.14</td>
</tr>
<tr>
<td>Dry matter conversion*</td>
<td>6.15</td>
<td>5.95</td>
<td>0.07</td>
<td>0.09</td>
</tr>
<tr>
<td>Daily DMI, lbs</td>
<td>20.4</td>
<td>20.4</td>
<td>0.10</td>
<td>0.94</td>
</tr>
<tr>
<td>Days on feed*</td>
<td>127</td>
<td>127</td>
<td>—</td>
<td>1.00</td>
</tr>
<tr>
<td>Removals, %</td>
<td>0.08</td>
<td>0.32</td>
<td>0.18</td>
<td>0.37</td>
</tr>
</tbody>
</table>

*Includes weight of removals but not deacts

Summary

- Titanium 3 yielded comparable results to Pyramid 2 + Type II BVD in health and performance parameters in winter placed calves
**Micotil® 300 Injection**

**Tilmicosin Injection, USP**

**Indications:** Tilmicosin is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni and for the treatment of ovine respiratory disease (ORD) associated with Mannheimia haemolytica. Micotil is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with Mannheimia haemolytica.

**Dosage and Administration: Inject Subcutaneously in Cattle and Sheep Only.** In cattle, administer a single subcutaneous dose of 10 to 20 mg/kg of body weight (1 to 2 mL/kg or 1.5 to 3 mL per 100 lbs). In sheep greater than 15 kg, administer a single subcutaneous dose of 10 mg/kg of body weight (1 mL/kg or 1.5 mL per 100 lbs). Do not inject more than 10 mL per injection site.

If no improvement is noted within 48 hours, the diagnosis should be reevaluated.

For cattle and sheep, injection under the skin in the neck is suggested. If not accessible, inject under the skin behind the shoulder and over the ribs.

**Note:** Swelling at the subcutaneous site of injection may be observed.

**Contraindications:** Do not use in automatically powered syringes. Do not administer intravenously to cattle or sheep. Intravenous injection in cattle or sheep will be fatal. Do not use in lambs less than 15 kg body weight.

Do not administer to animals other than cattle or sheep. Injection of this antibiotic has been shown to be lethal in swine and non-human primates, and it may be fatal in horses and goats.

**Warnings:**

**Human Warnings:** Not for human use. Injection of this drug in humans has been associated with fatalities. Keep out of reach of children. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply ice or cold pack to injection site while avoiding direct contact with the skin. Emergency medical telephone numbers are 1-800-722-0670 or 1-400-528-4441. Avoid contact with eyes.

**Adverse Reactions:** The following adverse reactions have been reported post-approval: In cattle, injection site swelling and inflammation, lameness, collapse, anaphylaxis/anaphylactoid reactions, decreased food and water consumption, and death. In sheep, lameness and death. For a complete listing of adverse reactions for tilmicosin phosphate reported to the FDA see http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055394.htm

**Clinical Pharmacology:** A single subcutaneous injection of Micotil at 10 mg/kg of body weight dose in cattle resulted in peak tilmicosin levels within 1 hour and detectable levels (0.07 g/mL) in serum beyond 3 days. However, lung concentrations of tilmicosin were elevated above the tilmicosin MIC 95% of 3.12 mg/L for Mannheimia haemolytica for at least 7 days after the single injection. Serum tilmicosin levels are a poor indicator of total body tilmicosin. The lung/gut tilmicosin ratio in favor of lung tissue appeared to stabilize by 3 days post-injection at approximately 60. In a study with radiolabeled tilmicosin, 24% and 69% of the dose was recovered from urine and feces respectively over 21 days. After a single subcutaneous injection of Micotil at 10 mg/kg of body weight, tilmicosin concentrations in excess of 4 mg/L were maintained in the alveolar macrophages and neutrophils of most cattle for at least 10 days. The clinical relevance of these findings has not been determined.

**Microbiology:** Tilmicosin has an in vitro antibiotic spectrum that is predominantly Gram-positive with activity against certain Gram-negative microorganisms. In vivo activity against several Mycoplasma species has also been observed.

**Effectiveness:** In a multi-location field study, 1508 calves with naturally occurring BRD were treated with Micotil. Responses to treatment were compared to saline-treated controls. A cure was defined as a calf with normal appetite and activity, normal respiration, and a rectal temperature of ≤104°F on Day 13. The cure rate was significantly higher (P<0.004) in Micotil-treated calves (83.1%) compared to saline-treated calves (29.5%). During the treatment phase of the study, there were 10 BRD-related deaths in the Micotil-treated calves compared to 47 in the saline-treated calves.

**Animal Safety:** A safety study was conducted in feeder calves receiving subcutaneous doses of 30, 30, or 60 mg/kg of body weight, injected 3 times at 72-hour intervals. Death was not seen in any of the treatment groups. Injection site swelling and mild hemorrhage at the injection site were seen in animals in all dosage groups. Lesions were described as being generally more severe and occurred at higher frequency rates in the animals treated with higher doses of tilmicosin. Laminen associated with the injection site was noted in two of twenty-four animals (one animal in the 30 mg/kg body weight treatment and one animal in the 60 mg/kg treatment group). No other drug related lesions were observed macroscopically or microscopically. Decreases in food and water consumption were noted in all treatment groups compared to the control group.

A separate safety study conducted in feeder calves, subcutaneous doses of 15, 30, or 50 mg/kg of body weight, injected 3 times at 72-hour intervals did not cause any deaths. Ewes at the site of injection was noted. The only lesion observed was necrosis in minimal myocardial necrosis in some animals dosed at 50 mg/kg.

In an additional safety study, subcutaneous doses of 150 mg/kg body weight injected at 72-hour intervals resulted in death of two of the four treated animals. Ewes was marked at the site of injection. Minimal myocardial necrosis was the only lesion observed at necropsy. Deaths of cattle have been observed with a single intravenous dose of 5 mg/kg of body weight.

In sheep, subcutaneous injection of 10 mg/kg body weight did not cause any deaths and no adverse effects of tilmicosin were observed on blood pressure, heart rate, or respiratory rate.

**Exercise:** Tilmicosin is a beta-agonist designed for use in cattle, sheep, goats, horses and swine. The beta-agonistic effects are increased heart rate (lactancia) and increased contractility (negative inotropy). Cardiovascular toxicity may be due to calcium channel blockade.

**Adverse Effects:** Upon subcutaneous injection, the acute median lethal dose of tilmicosin in mice is 9 mg/kg and in rats is 185 mg/kg of body weight. Given orally, the median lethal dose is 1000 mg/kg and 2000 mg/kg in fasted and nonfasted rats respectively. No compound-related necrosis was observed.

In dogs, intravenous calcium offset-Micotil-induced tachycardia and negative inotropy, restoring arterial pulse pressure. Dogs exhibited an initial transient offset the negative inotropy of Micotil-induced hypotension. No other observed effects were noted.

In pigs, dogs, intravenous calcium offset-Micotil-induced tachycardia and negative inotropy, restoring arterial pulse pressure. Dogs exhibited an initial transient offset the negative inotropy of Micotil-induced hypotension. No other observed effects were noted.

In monkeys, a single intravenous dose of 10 mg/kg body weight caused no signs of toxicity. A single dose of 20 mg/kg body weight caused vomiting and 30 mg/kg body weight caused the death of the only monkey tested.

In swine, intravenous injection of 10 mg/kg body weight caused increased respiration, emesis, and a convolution. 20 mg/kg body weight resulted in mortality in 3 of 4 pigs, and 30 mg/kg caused the death of all 4 pigs tested. Signs of 4.5 and 5.6 mg/kg body weight intravenously followed by ethylmorphine 1 mL/100 kg intramuscularly 2 to 6 times, resulted in death in all pigs injected. Piglets given 20 mg/kg intravenous with no ethylmorphine all survived. These results suggest intravenous ethylmorphine may be contraindicated.

Results of genetic toxicology studies were all negative. The dominant lethal and spermicidal studies in rats were negative. The no effect level in dogs after daily oral doses for up to one year 4 mg/kg of body weight.

**Storage Conditions:** Store at or below 68°F (20°C). Protect from direct sunlight.

**Conservar a 68°F (20°C). Proteje de la luz solar directa.**

**How Supplied:** Micotil is supplied in 100 mL and 250 mL multi-dose amber glass bottles.

**Manufactured for:** Elanco Animal Health • A Division of Eli Lilly and Company • Indianapolis, IN 46285, USA

**Revised January 2010**

*Micotil® is a trademark of Eli Lilly and Company.

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**Final Report # AHIS-2014-ELANCO-02. A Comparative Study on the Efficacy of Titanium 3 to Pyramidal 2 + Type II BYD in the Prevention of Bovine Respiratory Disease.**

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