Animals should be appropriately administered. Use sterile equipment. Inject under the skin in front of the shoulder (see illustration).

CONTRAINDICATIONS
As with all drugs, the use of ZACTRAN is contraindicated in animals previously found to be hypersensitive to this drug.

WARNING: FOR USE IN CATTLE ONLY. NOT FOR USE IN HUMANS.
KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN. NOT FOR USE IN CHICKENS OR TURKEYS.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance, or to obtain a copy of the SDS, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or online at www.fda.gov/reportanimaladverse.

RESIDUE WARNINGS: Do not treat cattle within 35 days of slaughter. Because a discard time in milk has not been established, do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
READ ENTIRE BROCHURE CAREFULLY BEFORE USING THIS PRODUCT.

DESCRIPTION
ZACTRAN® Injection for Cattle is a ready to use sterile parenteral solution containing gamithromycin, a macroclide sub-class, 7-aza-azabiclic antimicrobial. Each mL of ZACTRAN contains 150 mg of gamithromycin as the free base, 1 mg of monohydrargylic alcohol and 40 mg of succinic acid as a crystalline gel formant.
The chemical name of gamithromycin is 1-D(3-aza-5-D-ribopyranosyl)-2-ethyl-3,4,10-trihydroxy-11,13,15,17-tetrahydro-3,5,8,10,12,14-hexamethyl-7-propyl-17-one,13-[(2,6-dideoxy-3-C-methyl-3-O-methyl-alpha-L-ribo-hexopyranosyl)(oxy)-1,28,35,38,45,55,58,88,108,118,125,135,148-ribo]-] and the structure is shown below.

INDICATIONS
ZACTRAN is indicated for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis in beef and non-lactating dairy cattle. ZACTRAN is also indicated for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with Mannheimia haemolytica and Pasteurella multocida.

DOSEAGE AND ADMINISTRATION
Administer ZACTRAN one time as a subcutaneous injection in the neck at 6 mg/kg of BW (12 mL/110 lb body weight (BW)). If the total dose exceeds 10 mL, divide the dose so that no more than 10 mL is administered at each injection site.

### Table 1. Gamithromycin minimum inhibitory concentration (MIC) values* of indicated pathogens isolated from BRD treatment field studies in the U.S.

<table>
<thead>
<tr>
<th>Indicated Pathogens</th>
<th>Year of isolation</th>
<th>No. of isolates</th>
<th>MIC** (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. haemolytica</td>
<td>2004</td>
<td>3</td>
<td>0.5 to 1</td>
</tr>
<tr>
<td>P. multocida</td>
<td>2004</td>
<td>5</td>
<td>0.25 to 1</td>
</tr>
<tr>
<td>M. somni</td>
<td>2004</td>
<td>2</td>
<td>0.5 to 1</td>
</tr>
</tbody>
</table>

* The correlation between in vitro susceptibility data and clinical effectiveness is unknown.

** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

EFFECTIVENESS
The effectiveness of ZACTRAN for the treatment of BRD associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni was demonstrated in a field study conducted at four geographic locations in the United States. A total of 497 cattle exhibiting clinical signs of BRD were enrolled in the study. Cattle were administered ZACTRAN (6 mg/kg BW) or an equivalent volume of sterile saline as a subcutaneous injection on Day 0. Cattle were observed daily for clinical signs of BRD and were evaluated for clinical success on Day 10. The percentage of successes in cattle treated with ZACTRAN (98%) was statistically significantly higher (p<0.005) than the percentage of successes in the cattle treated with saline (19%).
The effectiveness of ZACTRAN for the treatment of BRD associated with M. bovis was demonstrated independently at two U.S. study sites. A total of 562 cattle exhibiting clinical signs of BRD were enrolled in the studies. Cattle were administered ZACTRAN (6 mg/kg BW) or an equivalent volume of sterile saline as a subcutaneous injection once on Day 0. At each site, the percentage of successes in cattle treated with ZACTRAN on Day 10 was statistically significantly higher than the percentage of successes in the cattle treated with saline (74.4% vs. 24% (p<0.001) and 67.4% vs. 46.2% (p<0.002)). In addition, in the group of calves treated with gamithromycin that were confirmed positive for M. bovis (pre-treatment nasopharyngeal swabs), there were more calves at each site (45 of 57 calves, and 5 of 6 calves) classified as successes than as failures.

The effectiveness of ZACTRAN for the control of respiratory disease in cattle at high risk of developing BRD associated with Mannheimia haemolytica and Pasteurella multocida was demonstrated in two independent studies conducted in the United States. A total of 467 crossbred beef cattle at high risk of developing BRD were enrolled in the study. ZACTRAN (6 mg/kg BW) or an equivalent volume of sterile saline was administered as a single subcutaneous injection within one day after arrival. Cattle were observed daily for clinical signs of BRD and were evaluated for clinical success on Day 10 post-treatment. In each of the two studies, the percentage of successes in the cattle treated with ZACTRAN (86% and 78%) was statistically significantly higher (p<0.0019 and p<0.0016) than the percentage of successes in the cattle treated with saline (36% and 58%).

ANIMAL SAFETY
In a target animal safety study in healthy, six-month old beef cattle, ZACTRAN was administered by subcutaneous injection at 6, 18, and 30 mg/kg body weight (1, 5, and 5 times the labeled dosage) on Day 0, 5, and 10 (3 times the labeled administration frequency). Injection site discomfort (neck twisting, attempts to scratch or lick the injection site, and pawing at the ground) was observed in calves in the 18 mg/kg BW and 30 mg/kg BW groups at 10 minutes post-treatment following each injection. Mild to moderate injection site swelling and pathology changes consistent with inflammation were observed in the gamithromycin-treated groups. Other than injection site reactions, no clinically relevant treatment-related effects were observed.

STORAGE CONDITIONS
Store at or below 77°F (25°C) with excursions between 59-86°F (15-30°C). Use within 18 months of first puncture.

HOW SUPPLIED
ZACTRAN is available in three ready-to-use bottle sizes. The 100, 250 and 500 mL bottles contain sufficient solution that will treat 10, 25 and 50 head of 550 lb (250 kg) cattle, respectively.

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