**INDICATIONS:**
Tenotryl™ is indicated for the treatment of SRD or as a control of SRD associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica and Mycoplasma hyopneumoniae*. Tenotryl™ is indicated for the control of colibacillosis associated with *Escherichia coli* and *Staphylococcus aureus*, and Gram-positive bacteria.

**EFFECTIVENESS:**
A total of 590 pigs were treated with enrofloxacin or saline in two separate natural infection SRD field trials. For the treatment of SRD, the success rate of enrofloxacin-treated pigs that were defined as "sick and febrile" (increased respiratory rate, labored or dyspneic breathing, depressed attitude and a rectal temperature ≥ 104°F) was statistically significantly greater than the success rate of saline-treated "sick and febrile" pigs. For the control of SRD, mean rectal temperature, mortality (one trial) and morbidity were statistically significantly lower for enrofloxacin-treated pigs in pens containing a percentage of "sick and febrile" pigs. The effectiveness of enrofloxacin administered as a single SC dose of 7.5 mg/kg BW for the treatment and control of SRD associated with *M. hyopneumoniae* was demonstrated using independent natural infection field studies and three single-site natural infection field studies. In the model study, 72 healthy pigs were challenged with a representative *M. hyopneumoniae* isolate and treated with enrofloxacin or saline. A statistically significant (P < 0.0001) decrease in the mean total lung lesion score was observed in the enrofloxacin-treated group (4%) compared with the saline-treated group (27%) at 10 days post-treatment. In two field studies evaluating effectiveness for the control of SRD, treatment of 300 pigs with clinical signs of SRD (moderate depression, moderately increased respiratory rate, and a rectal temperature of ≥ 104°F) were enrolled and treated with enrofloxacin or saline. At 7 days post-treatment, the cure rate was statistically significantly higher at each site (P < 0.0001) in the enrofloxacin-treated groups (61.3% and 92%) compared with the saline-treated groups (26.7% and 33.3%). In one field study evaluating effectiveness for the control of SRD, treatment of 1000 pigs in which > 15% had clinical signs of SRD (moderate depression score, moderately increased respiratory rate, and a rectal temperature of ≥ 104°F) was enrolled and treated with enrofloxacin or saline. At 7 days post-treatment, the cure rate was statistically significantly higher (P < 0.0002) in the enrofloxacin-treated group (70.0%) compared with the saline-treated group (48.5%). In addition to *M. hyopneumoniae*, *B. bronchiseptica* was also isolated in sufficient numbers from these field studies to be included in the SRD treatment and control indications. The effectiveness of enrofloxacin for the control of colibacillosis associated with *E. coli* was evaluated in a multi-site natural infection field study. At each site, when at least 5% of the pigs were defined as "clinically affected" (presence of diarrhea and either depression or gauntness), all pigs were administered enrofloxacin as a single IM dose of 7.5 mg/kg BW for 3 days or an equivalent dose volume of saline. At 7 days post-treatment, the success rate was statistically significantly higher (P = 0.0350) in the enrofloxacin-treated group (61.5%) compared with the saline-treated group (44.7%). The effectiveness of enrofloxacin administered as a single IM dose of 7.5 mg/kg BW for the treatment and control of SRD or as a single SC dose of 7.5 mg/kg BW for the control of colibacillosis was confirmed by demonstrating comparable serum enrofloxacin concentrations following IM or SC injection into the neck of healthy male and female pigs.

**TOXICITY:**
The oral LD50 for laboratory rats was greater than 5000 mg/kg of body weight. Ninety-day feeding studies in rats revealed no observable adverse effects at treatment rates of 3 and 40 mg/kg respectively. Chronic studies in rats and mice revealed no observable adverse effects at 5, 25 and 323 mg/kg respectively. There was no evidence of carcinogenic effect in laboratory animal models. A two-generation rat reproduction study revealed no effect with 10 mg/kg treatments. No teratogenic effects were observed in rabbits at doses of 25 mg/kg or in rats at 50 mg/kg.

**ANIMAL SAFETY:**
**Subcutaneous Safety:** A safety study was conducted in 32 pigs weighing approximately 57 kg (125 lb) using single doses of 5, 15 or 25 mg/kg daily for 15 consecutive days. Incidental lameness of short duration was observed in all groups, including the saline-treated controls. Musculoskeletal stiffness was observed following the 15 and 25 mg/kg treatments with clinical signs appearing during the second week of treatment. Clinical signs of lameness improved after treatment ceased and most animals were clinical normal at necropsy. A second study was conducted in two pigs weighing approximately 23 kg (50 lb), treated with 50 mg/kg for 5 consecutive days. There were no clinical signs of toxicity or pathological changes. An injection site study conducted in pigs demonstrated that the formulation may induce a transient reaction in the subcutaneous tissue. No painful responses to administration were observed.

**Intramuscular Safety:** A safety study was conducted in 48 weaned, 20- to 22- day-old pigs. Pigs were treated with enrofloxacin, at 7.5, 22.5 and 37.5 mg/kg BW by IM injection into the neck once weekly for 3 consecutive weeks. All pigs remained clinically normal throughout the study. Transient decreases in feed and water consumption were observed after each treatment. Mild, transient, post-treatment injection site swellings were observed in pigs receiving the 37.5 mg/kg BW dose. Injection site inflammation was found to persist in less than 1% in enrofloxacin-treated groups.

**STORAGE CONDITIONS:**
Protect from direct sunlight. Do not refrigerate or freeze. Store at 20-30°C (68-86°F), excursions permitted between 15°C (59°F) to 40°C (104°F). Precipitation may occur due to cold temperature. To redissolve, warm and then shake the vial.

**HOW SUPPLIED:**
Tenotryl™ (enrofloxacin) Injectable Solution: 100 mg/ml, 100 mL Bottle

**REFERENCES:**

**ADVERSE REACTIONS:**
No adverse reactions were observed during clinical trials. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae.

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