

1196 Hwy. 3 South · Northfield, MN 55057 · 888-215-1256 · www.aurorapharmaceutical.com

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FOR IMMEDIATE RELEASE

Contact: Bob Rehurek Phone: 507-650-7204 Cell Phone: 651-269-0565 Email: <u>brehurek@aurorapharmaceutical.com</u>

FDA Approves Aurora's Equine antimicrobial oral suspension

Aurora Pharmaceutical is proud to announce the FDA approval of EQUISUL-SDT (Sulfadiazine/Trimethoprim) suspension. EQUISUL-SDT is FDA approved (NADA 141-360) for the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus*.

Produced using Aurora's patented drug product formulation; EQUISUL-SDT demonstrated 20% increased bioavailability over an existing paste product in a pharmacokinetic crossover study. EQUISUL-SDT is approved for oral administration at the dosage of 24 mg combined active ingredients per kilogram body weight (10.9 mg/lb.) twice daily for 10 days. EQUISUL-STD can be administered by volume at 2.7 ml per 45.4 kg (2.7 mL/100 lb.) body weight.

In a controlled field efficacy study of EQUISUL-SDT in horses with lower respiratory tract infections caused by *Streptococcus equi* subsp. *zooepidemicus*, 59% (66/112) of the horses receiving EQUISUL- SDT were successfully treated, showing complete resolution of clinical symptoms within seven days after completion of treatment. In contrast, only 15% of the negative control horses demonstrated improvement during the same period. Transtracheal wash samples taken before and after treatment indicated complete bacterial clearance of S. *equi* subsp. *zooepidemicus* in 66% of the treated horses. The incidences of adverse events associated with EQUISUL-STD treatment during this study were comparable to those seen in the saline control group and were largely self-limiting. Diarrhea was seen in only 1.1% of the horses treated and resolved without treatment.

In a controlled safety study, horses were administered up to five times the recommended dose of EQUISUL-SDT twice daily for 30 consecutive days. While a higher incidence of loose stool was seen in horses treated with the higher dose of EQUISUL-SDT, in all cases, the incidents were self-limiting and resolved without treatment. EQUISUL-SDT is the only sulfadiazine/trimethoprim product for horses to be tested according to modern FDA requirements.

Aurora Pharmaceutical has supply agreements with all major distributors throughout the United States. Please check the website, <u>www.aurorapharmaceutical.com</u>, for the list and contact information.

The product is available in 900 mL and 135 mL bottles.

If you would like more information, please contact Aurora customer service at 888-215-1256. ad000007 08/2013

We are creating the products you want by using innovative, state-of-the-art, environmentally friendly technologies.