

Sunday - 10:00AM-10:15AM

Safety of Moxidectin Canine SR (Sustained Release) Injectable in Ivermectin-Sensitive Collies and in Naturally Infected Mongrel Dogs.

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Fifteen heartworm-free, ivermectin-sensitive purebred collies and twenty mongrel dogs harboring adult heartworms and circulating microfilariae were used to evaluate the safety of a single dose of moxidectin canine SR injectable. Moxidectin canine SR injectable was evaluated at the proposed label dose (0.17 mg moxidectin/kg body weight), and at three and five times the proposed label dose in the collies, and at three times the proposed label dose in the mongrel dogs. In each case, moxidectin canine SR injectable was administered subcutaneously.

**Part A: Safety in ivermectin sensitive collies.** Only collies that demonstrated ivermectin sensitivity after administration of ivermectin at 120 µg/kg were used. After acclimation, dogs were randomly assigned to a treatment group with approximately one half treated in each treatment group on day zero and the other half treated on day twenty one. Non-treated dogs served as controls on corresponding treatment days. Dogs were observed, by personnel blinded to treatment, for clinical signs of moxidectin toxicity twice daily after treatment for 21 days. On treatment days, dogs were observed prior to treatment, hourly for the first eight hours post-treatment, and 12 and 18 hours post-treatment. Scores for depression, ataxia, mydriasis, and salivation were recorded at each of these times. No adverse reactions to moxidectin treatment were recorded for any dog during the study period. These results demonstrated the safety of moxidectin canine SR injectable at dosages up to five times the recommended dose to collies known to be sensitive to 120 µg ivermectin/kg body weight.

**Part B: Safety in heartworm-positive dogs.** The twenty mixed-breed dogs were confirmed heartworm positive by use of a commercial antigen test and the modified Knott's test. They were allocated to two groups of 10 dogs. Dogs in one of the two groups were treated on study Day 0 with moxidectin canine SR injectable. Dogs in the remaining group were not treated. Pretreatment (Day -1) and exit (Day 28) physical examinations were performed on all dogs. All dogs were examined twice daily for any adverse health events. A blood specimen was collected on each of study Days -14, 7, 14, 21, and 28 for determination of numbers of circulating microfilariae. All dogs were subjected to necropsy examination on study day 28 for recovery and enumeration of adult heartworms. No adverse health effects were observed following treatment with moxidectin. Based on geometric means, reductions in microfilarial counts in treated dogs compared to control dogs on study Days 7, 14, 21, and 28 were 97.62%, 98.98%, 99.60%, and 99.49%, respectively. Geometric mean numbers of live adult heartworms recovered from treated and control dogs were 24.1 and 29.1, respectively. These results indicate that a 3x dose of moxidectin canine SR injectable formulation (0.51 mg moxidectin/kg body weight) does not induce adverse effects if administered to dogs harboring adult *D. immitis* and circulating microfilariae.

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