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Imidacloprid/moxidectin topical solution for the prevention of heartworm disease and the treatment and control of flea and intestinal nematodes of cats

R.G. Arther *, S. Charles, D.K. Ciszewski, W.L. Davis, T.S. Settje

Bayer HealthCare, Animal Health Division, 12707 W. 63rd St., Shawnee Mission, KS 66216, USA

Abstract

Sixteen controlled laboratory studies, involving 420 kittens and cats, were conducted to evaluate the efficacy and safety of topically applied formulations of imidacloprid and moxidectin for the prevention of feline heartworm disease, treatment of flea infestations and treatment and control of intestinal nematodes. Unit-dose applicators and the dosing schedule used in these studies were designed to provide a minimum of 10 mg imidacloprid and 1 mg moxidectin/kg. Treatments were applied topically by parting the hair at the base of the skull and applying the solution on the skin. Imidacloprid treatment alone did not display activity against *Dirofilaria immitis* or intestinal nematodes and moxidectin treatment alone provided little or no activity against adult *Ctenocephalides felis* infestations. The formulation containing 10% imidacloprid and 1% moxidectin was 100% efficacious against the development of adult *D. immitis* infections when cats were treated 30 days after inoculation with third-stage larvae. A single treatment with this formulation also provided 88.4–100% control of adult *C. felis* for 35 days. Imidacloprid/moxidectin was 100% efficacious against adult *Toxocara cati* and 91.0–98.3% efficacious against immature adults and fourth-stage *T. cati* larvae. The formulation provided 98.8–100% efficacy against adult *Ancylostoma* and immature adults and third-stage *A. tubaeforme* larvae. Monthly topical application with 10% imidacloprid/1% moxidectin is convenient, efficacious and safe for the prevention of feline heartworm disease, treatment of flea infestation and for the treatment and control of intestinal nematode infections of cats.
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Keywords: *Ancylostoma*; *Ctenocephalides felis*; *Dirofilaria immitis*; Imidacloprid; Moxidectin; *Toxocara cati*; Feline heartworm

1. Introduction

A novel solution containing 10% imidacloprid/1% moxidectin was evaluated for monthly topical application to kittens and cats for the prevention of feline heartworm disease caused by *Dirofilaria immitis*, for treatment of flea infestations (*Ctenocephalides felis*) and for the treatment and control of intestinal nematode infections caused by *Toxocara cati* and *Ancylostoma* spp. The combination product was formulated using the insecticide imidacloprid combined with moxidectin, a macrocyclic lactone

* Corresponding author. Tel.: +1 913 268 2503; fax: +1 913 268 2541.
E-mail address: bob.arther.b@bayer.com (R.G. Arther).

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endectocide. Imidacloprid is currently marketed worldwide as a 10% (w/v) (9.1%, w/w) solution for monthly topical treatment of fleas on cats and dogs (Advantage, Bayer HealthCare). Imidacloprid applied monthly as a low-volume topical application to dogs or cats provides highly effective flea control (Arther et al., 1997, Jacobs et al., 1997). Fleas are immobilized and killed after contact with imidacloprid on the skin or hair of treated animals (Mehlhorn et al., 1999). A moxidectin oral tablet formulation was previously developed as a monthly treatment for the prevention of heartworm disease in dogs (McCall et al., 1992a; McTier et al., 1992), and more recently, moxidectin was formulated as a sustained-release injectable for heartworm prevention (Lok et al., 2001). The new topical formulation of 10% imidacloprid/1% moxidectin solution was produced by replacing a proportion of the pharmaceutically inactive component of the commercial Advantage formulation with moxidectin.

2. Materials and methods

Sixteen controlled laboratory studies were conducted to evaluate the efficacy and safety of topically applied formulations of imidacloprid and moxidectin. Test animals included 420 healthy, pre-conditioned long- and short-haired, mixed-breed kittens and cats, 8 weeks of age and older. Common protocol procedures were followed for each study in accordance with the U.S. Food and Drug Administration/Center for Veterinary Medicine, Good Target Animal Study Practices (May 1997). The animals were acclimated to the test facilities at least 7 days prior to study initiation. All study animals were handled similarly with due regard for their welfare and housed in individual cages in climate-controlled rooms. Cages were cleaned daily and minimum/maximum temperatures and relative humidity of the facilities were monitored. Care and housing of the animals was in full compliance with applicable animal welfare requirements. No medications or therapies, other than test articles or placebo, were administered to the cats during these trials. Experimental nematode infections required in some of these studies were established in accordance with the U.S. Food and Drug Administration/Center for Veterinary Medicine Guideline 36: Efficacy of Canine/Feline Anthelmintics (July 1985).

Test articles and placebo for the studies were provided to investigators in pre-filled unit-dose applicator tubes containing 10% imidacloprid/1% moxidectin, 1% moxidectin mono solution, 10% imidacloprid mono solution or placebo (solution without active ingredient). Animals weighing 4.1 kg or less were treated with applicator tubes containing 0.4 mL of test article or placebo; animals weighting more than 4.1 kg were treated with applicator tubes containing 0.8 mL of test article or placebo. Test materials were stored in a secured location at ambient temperatures and in the dark while in custody at the study locations. In all studies, test article or placebo was applied topically to the cat by parting the hair at the base of the skull to deliver a minimum of 0.1 mL of solution/kg body weight on the skin. All cats were examined at specified intervals after treatment for local or systemic adverse events. Blinding procedures were followed to assure that study personnel responsible for observations and data collection were blinded to the treatment status of each animal.

2.1. Feline heartworm (*D. immitis*): two studies

Sixty mixed-breed cats (31 males and 29 females) 5–8 months of age were each inoculated with 100 third-stage *D. immitis* larvae on Day −30. On Day −1, the cats were blocked by gender and body weight and were randomized to treatment groups: 10% imidacloprid/1% moxidectin (20 cats), 1% moxidectin (10 cats), 10% imidacloprid (10 cats) or placebo solution (20 cats). The cats were treated once with the designated material on Day 0. The cats were euthanized, necropsied and examined for adult *D. immitis* within the heart, lungs, connecting vascular system and abdominal and thoracic cavities on Day 140 (170 days after infection).

2.2. Adult fleas (*C. felis*): two studies

Forty-eight short-haired cats (24 males and 24 females) were infested with 100 recently emerged adult *C. felis* on Day −5. Live fleas were combed from the cats with fine-toothed combs, counted and removed on Day −4. The cats were then randomized to treatment groups balanced by sex and pretreatment flea infestation. The cats were re-infested with 100 adult *C. felis* on Day −1. On Day 0, treatments: 10%

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