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Clinical evaluation of the safety and efficacy of 10% imidacloprid + 2.5% moxidectin topical solution for the treatment of ear mite (*Otodectes cynotis*) infestations in dogs

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ABSTRACT

A clinical field investigation was conducted to evaluate the safety and efficacy of 10% imidacloprid/2.5% moxidectin for the treatment of ear mites (*Otodectes cynotis*) in dogs. The study was a multi-centered, blinded, positive controlled, randomized clinical trial conducted under field conditions with privately owned pets. A total of 17 veterinary clinics enrolled cases for the study. An otoscopic examination was performed to confirm the presence of *O. cynotis* residing in the ear of the dog prior to enrollment. A single-dog household was enrolled in the study if the dog had 5 or more ear mites and an acceptable physical examination. A multi-dog household was eligible if at least one dog in the household had 5 or more mites and all dogs in the household had acceptable physical exams and met the inclusion criteria. Qualified households were randomly assigned to treatments to receive either 10% imidacloprid + 2.5% moxidectin topical solution or topical selamectin solution (positive control product) according to a pre-designated enrollment ratio of 2:1, respectively. If more than one dog in a multiple dog household had adequate numbers of ear mites, one dog was randomly selected to represent the household for efficacy evaluation prior to treatment. Treatments were administered twice per label and dose banding directions for each product approximately 28 days apart (Days 0 and 28), by the dog's owner at the study site. All dogs in a household were treated on the same day and with the same product. The owners completed a post-treatment observation form one day after each treatment. Post-treatment otoscopic examinations were performed by the investigators or attending veterinarian on Days 28 and 56. Physical examinations were performed on Days 0 and 56.

One hundred and four (104) households were evaluated for efficacy on SD 28, and 102 households were evaluated for efficacy on SD 56. The dogs' ages ranged from 2 months to 16 years. A total of 247 dogs were evaluated for safety.

Percent efficacy was based on the percentage of dogs cleared of ear mites. Mite clearance on Day 28 was 71% for the imidacloprid + moxidectin group and 69% for the selamectin group.

Mite clearance on Day 56 was 82% for the imidacloprid + moxidectin group and 74% for the selamectin group. No serious adverse events associated with either product were observed during the study.

The study demonstrated that 10% imidacloprid + 2.5% moxidectin applied using two topical treatments, 28 days apart, was safe and achieved similar efficacy against *O. cynotis* as selamectin treatments applied and evaluated under the same conditions.

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1. Background

The ear mite *Otodectes cynotis* is a common mange mite of dogs and cats and is found world wide. The mites do not burrow but live on the surface of the skin of the ear canal where they feed on epidermal debris and tissue fluid from the superficial epidermis. Infestations are generally bilateral. As the mites feed, the epithelium of the ear canal fills with cerumen, blood, and mite debris. Frequently the discharge has a classic coffee ground appearance. Clinical signs including pruritus and head shaking are variable and frequently subclinical. Complications may arise in animals that have an immune hypersensitivity reaction resulting in intense irritation. Secondary bacterial infection may result in purulent otitis externa. The mites are not host specific, are highly contagious, and are transferred by direct contact. Infestations are prevalent in animal shelters and breeding establishments (Arther, 2009; Scott et al., 2001). It has been estimated that 50% of all otitis externa in dogs are caused by *O. cynotis* (Wall and Shearer, 2001). A topical formulation containing 10% imidacloprid + 1% moxidectin (Advantage® Multi for Cats, Bayer HealthCare, Animal Health) is currently approved for the treatment and control of ear mites (*O. cynotis*) in cats. The efficacy of this product has been reported (Davis et al., 2007; Fourie et al., 2003; Farkas et al., 2007). A topical formulation containing 10% imidacloprid + 2.5% moxidectin (Advantage® Multi for Dogs, Bayer HealthCare, Animal Health) is labeled for the prevention of heartworm disease, treatment of flea infestations, treatment and control of intestinal parasite infections, and for the treatment and control of sarcoptic mange mites (*Sarcoptes scabiei*) of dogs. The efficacy of this formulation for the treatment of *O. cynotis* infestations in dogs has previously been reported from a field study conducted in Europe (Krieger et al., 2005). The purpose of this study was to evaluate the safety and efficacy of 10% imidacloprid + 2.5% moxidectin for the treatment of *O. cynotis* infestations of dogs presented to multiple clinic locations in the United States.

2. Materials and methods

The study was conducted in accordance with the principles of FDA Guidance for Industry 85, Good Clinical Practice, VICH GL9, May 2001.

The study was conducted as a multi-centered field safety and efficacy trial using client owned dogs with clinical evidence of ear mite infestation. The study was designed as a blinded, positive controlled, randomized clinical trial to evaluate the safety and efficacy of the investigational veterinary product (IVP), 10% imidacloprid + 2.5% moxidectin (Advantage® Multi for Dogs, Bayer HealthCare, Animal Health) against *O. cynotis*. The positive control product (CP), 6 or 13% selamectin (Revolution®, Zoetis), was selected since this product is currently approved for the treatment of *O. cynotis* infestations of dogs.

Prior to enrollment, otoscopic examinations were conducted on the ears of dogs suspected of having ear mite infestation. The following criteria were required for study inclusion:

- Clinical signs suggestive of ear mites (e.g. shaking head, scratching at ears, exudate in ear canal)
- At least 7 weeks of age
- Body weight of 3 pounds or greater
- Each household was required to have at least one dog with 5 or more live mites in one or both ears
- Adequate health, except for ear mites
- A negative heartworm test for dogs greater than 6 months of age
- Owner willing to enroll his or her dog(s) in a clinical study, able to apply product, capable of reading and following instructions, willing to record post treatment observations, and willing to return the animal to the clinic at the designated times

For multiple dog households, only one dog from the household which met all of the inclusion criteria was used for efficacy determination. All dogs in the household, however, received two physical examinations, and were treated with the IVP or CP for safety evaluations even if all other pre-treatment efficacy requirements were not met.

Households were randomized to two different groups. The dog(s) in group 1 households were treated topically with the IVP. Dog(s) in group 2 households were treated topically with the positive CP. The ratio of IVP to CP households was approximately 2:1. The IVP and CP were provided in commercial prefilled applicator tubes. All dogs in a household received the same treatment. The owner applied the treatment to the dog(s) at the study site under the observation of clinic personnel.

For the IVP, the entire contents of the applicator tube size corresponding to the body weight of the dog were applied. It was recommended that the dog stand for the application. The hair was parted on the back of the dog between the shoulder blades until the skin was visible. For dogs weighing 20 lbs. or less, the tip of the tube was placed on the skin at one spot between the shoulder blades and the contents applied directly on the exposed skin. For dogs weighing more than 20 lbs the contents were applied directly on the exposed skin at 3 or 4 spots on the top of the backline from the base of the neck to the upper back in an area inaccessible to licking. The solution was not applied at any one location that could run off the side of the dog. For the first 30 min after application, steps were taken to ensure that all dogs could not lick the product from the application site on themselves and other treated dogs, and to separate treated dogs from one another to reduce the risk of accidental ingestion.

For the CP the entire contents of the applicator tube that corresponded to the body weight of the dog were applied. The hair on the back of the animal at the base of the neck in front of the shoulder blades was parted until the skin was visible. The tip of the tube was placed on the skin and the tube squeezed 3 or 4 times to empty its entire contents directly onto the skin in one spot.

Each dog was treated twice with either the IVP or CP (Days 0 and 28, ±3 days).

Post-treatment observations were conducted by the owners. One day following each treatment, the owner recorded the health status of the dog. If Adverse Events

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