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Efficacy against nematode and cestode infections and safety of a novel topical fipronil, (S)-methoprene, eprinomectin and praziquantel combination product in domestic cats under field conditions in Europe

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ABSTRACT

A novel topical combination product (BROADLINE®, Merial) composed of fipronil, (S)-methoprene, eprinomectin and praziquantel was evaluated for safety and efficacy against nematode and cestode infections in domestic cats. The study comprised a multi-centre, positive control, blinded, field study, using a randomized block design based on order of presentation for allocation. In total 196 client-owned cats, confirmed as positive for naturally acquired infections of nematodes and/or cestodes by pre-treatment faecal examination, were studied in seven countries in Europe. Pre-treatment faecal examination revealed the presence of *Toxocara*, hookworm, *Capillaria* and/or spirurid nematode infections in 129, 73, 33 or 1 cat(s), respectively; infections with taeniid and *Dipylidium* cestodes were demonstrated in 39 and 17 cats, respectively. Cats were allocated randomly to one of two treatments in a ratio of 2, topical fipronil (8.3%, w/v), (S)-methoprene (10%, w/v), eprinomectin (0.4%, w/v) and praziquantel (8.3%, w/v) (BROADLINE®, Merial; 130 cats); and 1, topical PROFENDER® Spot-On (Bayer; 66 cats) and treated once on Day 0. For evaluation of efficacy, two faecal samples were collected, one prior to treatment (Day -4 ± 4 days) and one at the end of the study (Day 14 ± 5 days). These were examined for fecal forms of nematode and cestode parasites. For evaluation of safety, cats were examined by a veterinarian before treatment and at the end of the study, and cat owners recorded the health status of their cats daily until the end of the study.

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For cats treated with Broadline®, the efficacy was >99.9%, 100%, and 99.6% for *Toxocara*, hookworms, and *Capillaria*, respectively; and the efficacy was >99.9%, >99.9%, and 98.5%, respectively, for the cats treated with Profender® ($p < 0.001$ for all nematodes and both treatments). Efficacy was 100% for both cestodes for both treatments ($p < 0.001$).
No treatment related adverse experiences were observed throughout the study. For both treatments, every cat that completed the study was given a safety score of 'excellent' for both local and systemic evaluations. The topical combination product of fipronil, (S)-methoprene, eprinomectin and praziquantel was shown to have an excellent safety profile and demonstrated high levels of efficacy when administered once as topical solution to cats infected with nematodes and cestodes under field conditions.
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1. Introduction

Cats are hosts to a variety of internal parasites comprising protozoa, trematodes, cestodes, nematodes, and a few acanthocephalans. Some of these parasites, usually depending on their abundance, may impact the health of cats and are known to cause problems ranging from retarded growth or failure to thrive up to clinical intestinal disorders, such as diarrhoea or respiratory disease. In addition, cats, like other companion animals, represent potential reservoirs, carriers and transmitters of several diseases including zoonotic parasitic infections.

The most common helminth parasites of cats worldwide are parasites of the gastrointestinal tract: ascarids (*Toxocara cati* and, with substantially lower prevalence and abundance, *Toxascaris leonina*), hookworms (mainly *Ancylostoma tubaeforme* and, depending on climate, other *Ancylostoma* species and occasionally *Uncinaria stenocephala*), taeniid cestodes (predominately *Taenia taeniaeformis* but occasionally other *Taenia* species and on the rare occasion *Echinococcus multilocularis* in endemic areas) and tapeworms of the family Dipylidiidae (most commonly *Dipylidium caninum* but also species of *Diplopylidium* and *Joyeuxiella*). In addition, infections of cats by metastrongyloid and capillarid lungworms have been diagnosed with increasing frequency in the recent past.

Parasites of domestic cats in Europe have been studied extensively in previous years and nematode and cestode infections have been shown to be a common occurrence. However, factors like category of cats (e.g., stray, feral, shelter, cattery, well-cared-for pet), habitat (urban or rural), or general access to the outdoors, result in considerable variability in the prevalence of endoparasites (e.g., Borkovcová, 2003; Coati et al., 2003; Omeragić, 2003; Miró et al., 2004; Robben et al., 2004; Romaniuk et al., 2004; Ingstrup, 2008; Gracenea et al., 2009; Keidāns et al., 2009; Overgaauw et al., 2009; Duarte et al., 2010; Ładczuk and Balicka-Ramisz, 2010; Mircean et al., 2010; Traversa et al., 2010; Barutzki and Schaper, 2011; Claerebout et al., 2011; Knaus et al., 2011b; Becker et al., 2012; Mugnaini et al., 2012; Näreaho et al., 2012; Zanzani et al., 2012; Capári et al., 2013; Riggio et al., 2013).

Although intestinal helminth infections of cats may cause limited clinical signs, they may cause significant pathology and the presence of these parasites may be unacceptable to cat owners from aesthetic and hygienic points of view as well as for veterinary and medical reasons. Thus, appropriate management practices for the control of feline helminth infections are required including the use of efficacious and safe antiparasitic drugs.

This paper reports the results of a multi-centre field study which was designed to evaluate the efficacy of a novel topical fipronil, (S)-methoprene, eprinomectin and praziquantel combination against naturally acquired nematode and cestode infections and the safety of the product at the recommended commercial dose ranges in domestic cats.

2. Materials and methods

The study was designed in accordance with the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products – VICH GL7, "Efficacy of Anthelmintics: General Requirements" (Vercruysse et al., 2001) and "Efficacy of Anthelmintics: Specific Recommendations for Felines" VICH GL20 (Vercruysse et al., 2002), the "World Association for the Advancement of Veterinary Parasitology (WAAVP) guidelines for evaluating the efficacy of anthelmintics for dogs and cats" (Jacobs et al., 1994) and VICH GL9, entitled *Good Clinical Practice*. An Informed Consent and Agreement was obtained from the owners of the cats before enrolment.

All personnel involved in collecting efficacy and safety data, and the owners, were blinded to the treatment that had been assigned to the animals.

2.1. Study animals

Client-owned cats of any breed and sex, with a minimum age of two months and harbouring naturally acquired nematode and/or cestode infections, as confirmed by pretreatment fecal examination, were eligible to be included in the study. The cats were in good condition and no suspicion of parasitic infestation was made before examination. Fecal samples of 529 cats, from 284 owners, were collected at eight sites in seven European countries (Albania, 57 cats; Austria, 53 cats; Bulgaria, 47 cats; Germany 1, 26 cats; Germany 2, 37 cats; Hungary, 120 cats; Latvia, 74 cats; Lithuania, 115 cats) and subjected to coproscopical examination.

In total, 196 cats were confirmed as positive for naturally acquired infections of nematodes and/or cestodes and were enrolled (Albania, 33 cats/21 owners; Austria, 15 cats/7 owners; Bulgaria, 34 cats/18 owners; Germany 1, 16 cats/8 owners; Germany 2, 22 cats/12 owners; Hungary, 37 cats/25 owners; Latvia, 16 cats/16 owners; Lithuania, 23

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