TEXT

**PAPER**

Evaluation of spinosad for the oral treatment and control of flea infestations on dogs in Europe

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**Context**

Flea control remains an integral component of canine healthcare throughout much of Europe. The latest addition to the options available to veterinarians for this purpose is spinosad, a naturally occurring mixture of spinosyns A and D formed during a fermentation process. Spinosyns are tetracyclic macrolides with a unique ring system. They exhibit a novel mode of action primarily involving nicotinic acetylcholine receptor binding sites distinct from those targeted by other insecticides. Spinosad is presented for flea control as chewable tablets (Comfortis; Elanco). Preliminary studies indicated that effective control of *Ctenocephalides felis* on dogs could be achieved over a four-week period with dose rates of 30 mg spinosad/kg bodyweight or above. A minimum dose of 45 mg/kg was selected for European laboratory studies to ensure compliance with local regulatory requirements.

**Main conclusion**

Laboratory and field investigations in Europe confirmed that spinosad administered orally to dogs at a dose rate of 45 to 70 mg/kg is highly effective for the treatment and control of flea infestations on dogs, with activity against new infestations persisting for up to four weeks. The field performance of spinosad compared favourably with that of a reference product, selamectin (Stronghold; Pfizer).

**Approach**

Three laboratory and two multicentre field studies were conducted in compliance with international guidelines and ethical requirements. In laboratory studies, individually housed beagles were allocated to spinosad-treated or placebo-treated groups, each comprising six or more dogs. Efficacy was assessed by infesting dogs at intervals with 100 *C. felis* and counting the number of surviving fleas after 48 hours. Study 1 used unformulated spinosad powder at a dose rate of 45 mg/kg with fleas applied 21 and 28 days after dosing. Studies 2 and 3 used tablets providing 45 to 54 mg spinosad/kg, with fleas applied on the day before treatment (study 2) and on days 7, 14, 21 and 28 (both studies). Statistical comparisons were based on geometric means to account for skewness of data.

The field trials included a one-month study in five European countries (study 4) and a three-month study in France (study 5). Dogs naturally infested with at least 10 fleas were randomly assigned to two groups and treated monthly. Spinosad-treated dogs were administered whole tablets according to a schedule that allowed a minimum dose of 80 mg/kg. Selamectin was applied topically as a 0.8% solution (Comfortis; Elanco). Preliminary studies indicated that effective control of flea infestations on dogs could be achieved over a four-week period with dose rates of 30 mg spinosad/kg bodyweight or above. A minimum dose of 45 mg/kg was selected for European laboratory studies to ensure compliance with local regulatory requirements.

**Results**

Flea populations established on dogs one day before treatment were completely eliminated. Residual efficacies in the three laboratory studies were greater than 99 per cent at three weeks post-treatment, with values of 97.8, 96.5 and 96.5 per cent, respectively, on day 30. In the two field trials, data from 93 and 43 spinosad-treated dogs were compared with data from 93 and 71 selamectin-treated dogs, respectively. Group mean flea counts were initially between 29.7 and 40.7 fleas per dog, with individual counts up to 560 fleas. The flea burden of spinosad-treated dogs was reduced by 97 per cent 14 days after the first treatment and by 99.6 per cent at days 60 and 90. Corresponding figures for selamectin-treated dogs were significantly lower (P<0.05) at all time points (83.5 to 90.7 per cent at day 14, 97.8 per cent at day 60 and 98.2 per cent at day 90 after treatment). ‘Zero-flea’ values during the first month varied from 59.5 to 59.1 per cent for spinosad-treated dogs and from 26.6 to 34.1 per cent for selamectin-treated dogs; these values increased thereafter and became significantly different (P=0.042) by day 90 at 85.0 per cent and 67.1 per cent, respectively.

**Interpretation**

The performance of spinosad in field trials can be ascribed to its combined pulicidal attributes. Laboratory studies confirmed a strong initial ‘knockdown’ effect and persistent activity. A previous study by other workers demonstrated a rapid speed of kill, starting at 30 minutes, with 100 per cent of fleas dead or moribund within four hours. Spinosad thereby destroys newly acquired fleas before they reach maturity, as evidenced by the 99.8 per cent reduction in flea egg output recorded in that study. Thus, monthly treatments prevent new eggs replenishing the reservoir of fleas developing in the home, leading to a progressive reduction in host-seeking fleas. In the present study, flea burdens on spinosad-treated dogs were reduced by 99.6 per cent within 60 days, and the ‘zero-flea’ data suggest that infestations had been eliminated from up to 88 per cent of homes by day 90.

**Significance of findings**

Effective flea control is a three-stage process. First, the removal of fleas from an already infested host provides relief from discomfort. Secondly, the animal must be protected from reinfection by host-seeking fleas already in the household environment. Thirdly, the reservoir of off-host life-cycle stages must be abolished to provide long-term control. In this series of European studies, spinosad given orally at a dose-rate of 45 to 70 mg/kg fulfilled these criteria.
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