RESUMO - ENTOMOLOGIA E ACAROLOGIA

RANDOMIZED, BLINDED CLINICAL TRIALS DETERMINING THE EFFICACY OF WELLPETTM (OUROFINO SAÚDE ANIMAL LTDA.), A FLURALANER-BASED ECTOPARASITICIDE, ON THE CONTROL OF TICKS AND FLEAS IN EXPERIMENTALLY INFESTED DOGS

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Two GCP-compliant trials, conducted under WAAVP guidelines, evaluated efficacies of WellPet™ (Ourofino Saúde Animal Ltda.), a highly palatable 10–

22.5 mg/kg fluralaner tablet, against Rhipicephalus sanguineus sensu lato and Ctenocephalides felis felis in dogs. These had approval by the respective Ethics Committees, and ethical approval for parasite colonies (protocols 001/2023, 9812271021, 4313110419, 2886011223), in full regulatory compliance. One enrolled twelve (12–60 months; 8.9–21.5 kg) and another 16 (16–89 months; 8.6–13.25 kg) dogs, randomized into WellPet™ and negative control groups (n=6 or n=8 per group). These negative-controlled, parallel-group, randomized-block, blind-assessed studies were performed by independent veterinary teams from CROs. Infestations used 100 fleas and 50 ticks (adults =14 days old, unfed, 50:50 sex ratio) per dog, restrained by =1 minute and calmed for ~30 minutes. Parasite counts/removals happened 24–48 hours after each infestation (twice pre-treatment). Eligibility required =25% parasite retention. After treatments, weekly reinfestations with subsequent inspections/counts/removals were repeated at least 7 times, and efficacy was calculated from live flea and live attached tick counts. Normality of data was assessed by Shapiro–Wilk, group comparisons performed by ANOVA for parametric data or Kruskal–Wallis for non-parametric data, at 95% significance ($P = 0.05$). Pre-treatment counts did not differ between groups, while post-treatment control counts were consistently higher ($P < 0.05$), confirming significant reductions with WellPet™. Flea efficacy was 100% throughout =45 days in both trials, except for 99.7–99.9% indexes on days 7–28 of trial 2. Tick efficacy was 100% through Day +28 in trial 1, dropping gradually until 98% by Day +45, whereas in trial 2 efficacy was 100% except at D+21 (99.6%), D+42 (98.3%) and D+49 (98.8%). This lower fluralaner dose may improve safety by reducing chemical burden and expanding safety margins. Such strategy aims to maximize efficacy while minimizing adverse events, with sustained systemic exposure reflected by acaricide/insecticide efficacies of 98%/100% at Day 45. Data collection intentionally stopped then. A 45-day retreatment interval was selected as a resistance-management strategy, given that resistance can be driven by high reproductive rates and exposure to subtherapeutic concentrations due to operational failures or declining systemic levels, making maintenance of plasma concentrations above therapeutic thresholds essential to prevent survival/selection, particularly under high infestation pressure. Overall, these studies demonstrate robust 45-day control of fleas and ticks and support WellPet™ as a promising reduced-dose alternative

to conventional fluralaner, that preserves efficacy while potentially improving safety and treatment adherence.

Palavras-chave: acaricide; ctenocephalides felis felis; insecticide; rhipicephalus linnaei; rhipicephalus sanguineus sensu lato.