ESTEVE veterinaria

# CLINICAL EFFICACY OF LEISGUARD® FOR THE PREVENTION OF CANINE LEISHMANIOSIS IN AN ENDEMIC AREA WITH HIGH RISK OF INFECTION

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## OBJECTIVE

**The aim of the current study was to evaluate the efficacy of Leisguard® for the prevention of canine leishmaniosis in endemic areas with high risk of infection.**

## INTRODUCTION

Leisguard® is a domperidone-based oral suspension marketed for the treatment and prevention of canine leishmaniosis (canL) in several European countries.

The preventive efficacy of Leisguard®, when administered to healthy dogs living in endemic areas with high prevalence of canL, has been previously demonstrated in a 21-month clinical trial performed with 90 dogs in Valencia (Spain) (*LLinás et al. 2011*). According to the results of this trial, i) the overall risk (odds) for Leisguard® treated dogs to clinically develop canL is quite 7 times lower than for untreated animals, and ii) the efficacy attributable to Leisguard® is about 80%.

The current study was performed as an extension of the above mentioned clinical trial in order to corroborate its results. It was performed during the following sand fly season, in the same geographical area and by the same practitioners.

## MATERIAL AND METHODS

- Ninety-three clinically healthy dogs of different sex, age, weight and breed (Table 1), serologically negative to *Leishmania* (Direct Agglutination Test, DAT<1/400), were included in a historically controlled clinical trial performed under the authorization of the Spanish Medicines Agency (AEMPS).
- All dogs followed a prevention program consisting of two 30-day treatments with Leisguard® at 1ml/10kg/24h, at the beginning and at the end of the *Phlebotomus* season (May/June – September/October).
- No other preventive treatment or insect repellents were used during the study.
- Dogs underwent a 9-month follow-up period with periodic clinical examinations and serological determination of anti- *Leishmania* antibody titers.
- The obtained results were compared with those previously obtained by Llinás et al. (2011) in the negative control group at month 12, which acted as a 'historical control group'.

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|---|---|---|
| Sex | Female | 38 (41%) |
| n (%) | Male | 55 (59%) |
| Weight (kg) | Mean (SD) | 22.4 (12.2) |
| | range | 4-53 |
| Breed | Mongrel | 13 (14%) |
| n (%) | other* | 80 (86%) |

** up to 31 breed*

***Table 1.*** *Distribution of animal baseline characteristics.*

## RESULTS

- Although at the end of the study 7,5% of the treated dogs were seropositive (1 dog = 1/800 and 6 dogs = 1/1600), none of them had clinical signs related to the disease.
- When comparing the results of this study with those obtained in the 'historical control group' in terms of percentage of seropositive animals (Figure 1), the observed differences were statistically significant in favor of the group treated with Leisguard® (7.5% vs 35%; p<0.001).

  According to the above mentioned data, the preventive efficacy attributable to the treatment program with Leisguard® results to be 80%.
- In addition, the odds-ratio calculated with data from both groups is 6.6 (I.C. 95%=2.458-17.47) (p<0.001), thus indicating that **the overall risk (odds) for Leisguard® treated dogs to clinically develop canL is quite 7 times lower than for not treated animals**, similar to that found in the study of Llinás et al. (2011).
- Leisguard® was well accepted by all dogs and no adverse reactions were reported during the study.

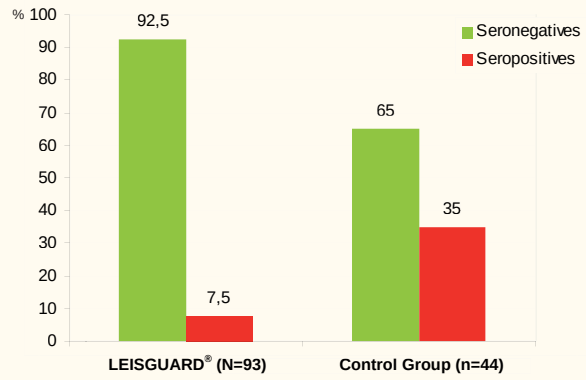


***Figure 1.*** *Distribution of seronegative vs seropositive animals in both groups.*

## REFERENCES

Llinás J, Gómez-Ochoa P, Sabaté D, Homedes J and Ferrer, L. Clinical efficacy of a domperidone-based treatment program for the prevention of canine leishmaniosis. Proceedings of the 46th AVEPA-SEVC Congress, 2011.

## CONCLUSIONS

**The results of this study confirm the excellent efficacy and safety of Leisguard® when administered for the prevention of canine leishmaniosis in endemic areas with high risk of infection.**