

Today we know a lot more
about how to prevent

Canine Leishmaniosis

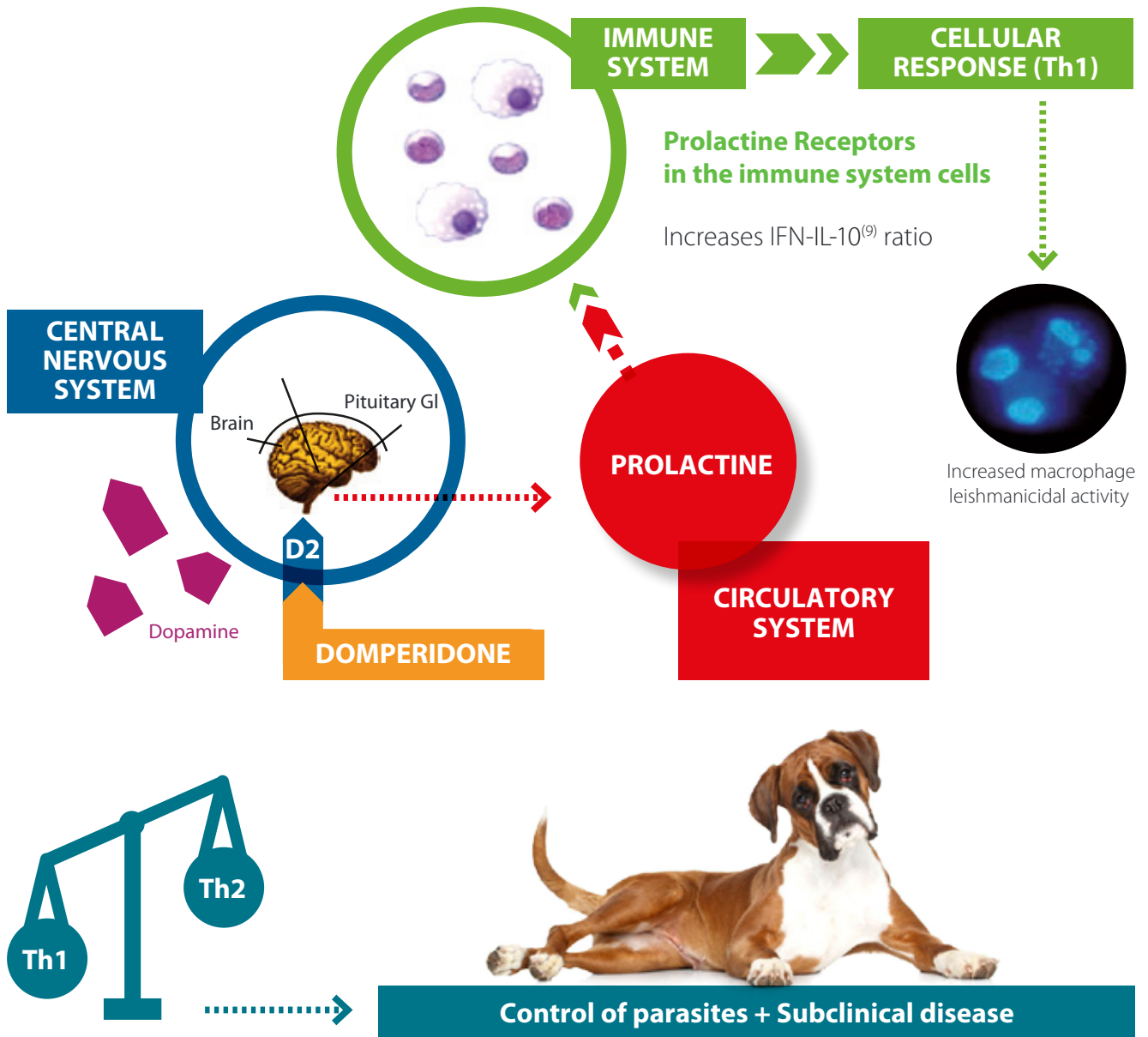


leiSguard®

1

KNOWN MODE OF ACTION

LEISGUARD® (domperidone) boosts **cell mediated immune response (Th 1)**¹



CELL MEDIATED IMMUNITY (Th 1) - active **since day 2 of treatment.**⁷

2

AN EFFECTIVE PREVENTIVE PROGRAMME

Best results of LEISPRO preventive programme are attained with:

- 1. LEISGUARD®:** in JUNE and OCTOBER
- 2. Sand flies (Phlebotomies) repellents** (May to October)
- 3. Serological test** (between February and April)



**Dose:
1 ml/10 kg BW
30 days**

Preventive programme



* The first serological testing at the beginning of the preventive programme must be quantitative, so that is more sensitive and specific. This, along with clinical exploration, will allow a better patient triage, and a better classification into healthy, infected or sick dogs.

3

ITS EFFECTIVENESS IS BASED...



Contents lists available at [ScienceDirect](#)

Preventive Veterinary Medicine

journal homepage: www.elsevier.com/locate/prevetmed



A single-centre, open-label, controlled, randomized clinical trial to assess the preventive efficacy of a domperidone-based treatment programme against clinical canine leishmaniasis in a high prevalence area



Prevention rate obtained with LEISGUARD® was **above 80%⁴**



Follow up of Leishmaniasis infection in an endemic area 1 year after the application of new preventive actions

Maria Dolores Tabar Rodríguez¹
¹Hospital veterinario San Vicente

0% Leishmaniasis incidence⁸
in dogs administered
with LEISGUARD®

VACCINATED dogs showed
a 8.2% Leishmaniasis incidence rate⁸

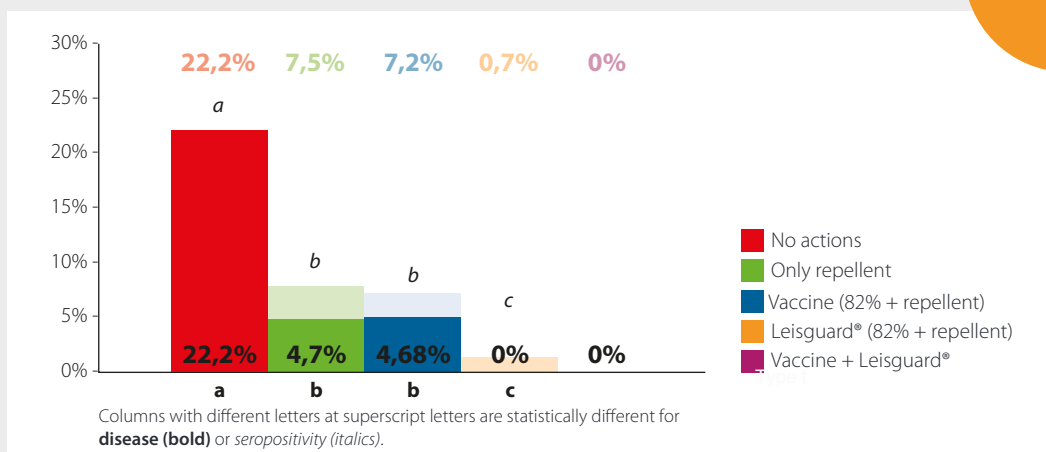


...ON THIS EVIDENCE

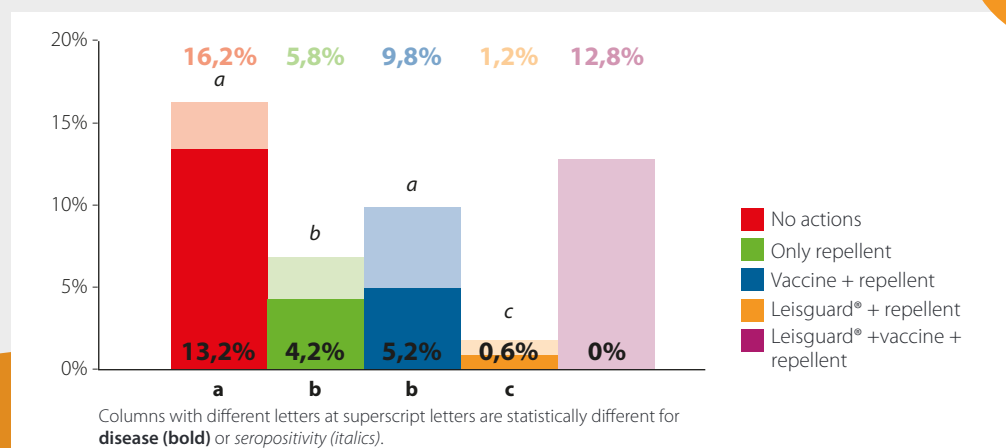
These multicentric studies (TESTIMONIALS) assessed the incidence of dogs that were Leishmania positive or sick at the end of the final follow up period and were performed on dogs that under went different prevention strategies.^{2,3}

Effectiveness and safety of various strategies to prevent canine leishmaniosis (available to purchase in May 2016):

Retrospective, multi centric study featuring 1077 cases in 28 veterinary centres (2012-2014).



Multicentric, retrospective study featuring 1695 cases in 51 Veterinary centres (2012 - 2016).



4

IN PUPPIES

...The only preventive option for puppies aged 6 months or less (except for repellents)

Leishmania infection presence is relevant at early ages and because of this, we must actively protect the puppies.

1. AGE:

13% of seropositive dogs are 1 year old or less.⁵

There is no minimum age to administer LEISGUARD® in puppies.¹

2. PREDISPOSED BREEDS:

Boxer, German shepherd, Rottweiler are more sensitive, and show higher prevalence of leishmaniasis.⁵

LEISGUARD® is different from vaccines as it protects the puppies at any age



STUDY OF THE EFFECT OF LEISGUARD ON THE EFFECTIVENESS OF A STANDARD VACCINATION SCHEDULE IN PUPPIES

Salichs M*, Sabaté D*, Rodón J# y Homedes J*

* Dpto. I+D Esteve veterinaria, ESTEVE, Barcelona (Spain)

#Laboratorio IDEXX Vet Lab, Plomo, 2-8 - 3ª planta; Barcelona, (Spain)

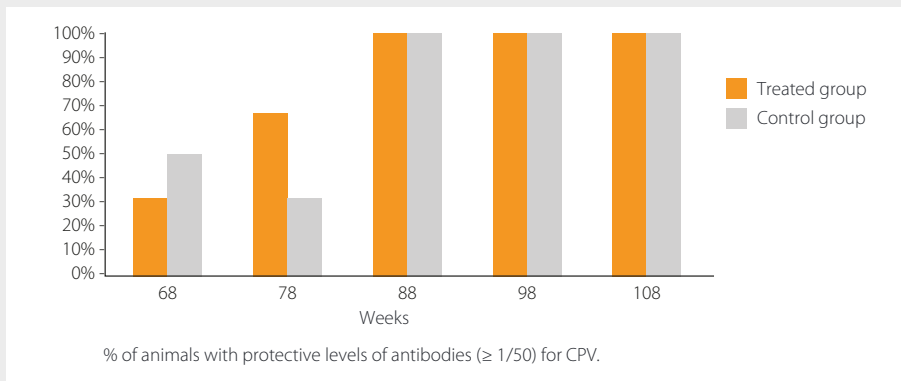
...An exclusive prevention

3. THE PREVENTION PLAN IS COMPATIBLE WITH THE STANDARD VACCINATION SCHEDULE IN PUPPIES

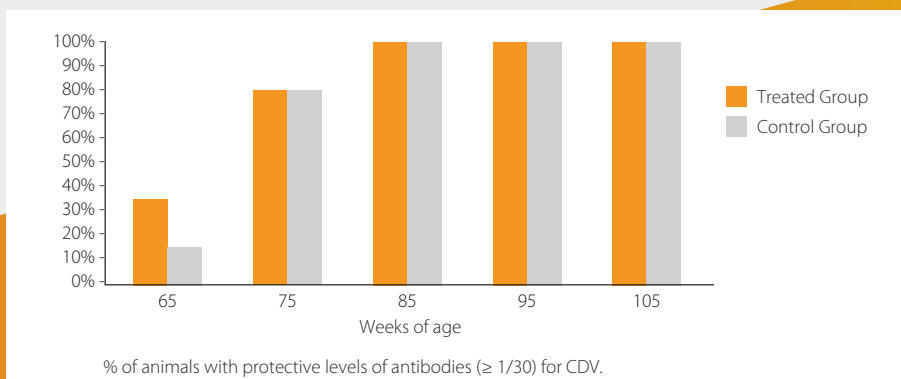
LEISGUARD Leishmaniasis Prevention programme

Can begin at the same time as the puppies vaccination schedule, at 6-8 weeks old.⁶

6 weeks vaccination	Leisguard®	8 weeks vaccination	Leisguard®
CPV, CDV	1 ml/10kg/day 14 days	CPV, CDV, CAV	-----
CPV, CDV	-----	CPV, CDV, CAV	-----
CPV, CDV	-----	CPV, CDV, CAV	Leisguard®
CPV, CDV	-----	CPV, CDV, CAV	-----



LEISGUARD® administration does not alter the speed or the intensity of the production of protective levels of antibodies for Parvovirus, Distemper virus, Hepatitis after standard vaccination schedules in puppies.⁶



5

SMALL BREEDS ...prevention with good tolerability



These breeds are more sensitive to vaccinations and other treatments **and are more eager to show side effects**

LEISGUARD® for small breeds - Benefits:

1. BETTER TOLERABILITY: Less and milder side effects.^{2,3}

Product	n	Incidence	Description
Repellent	8/1511 ^a	0,5%	1 Anaphylactic reaction 6 Rash at inoculation point 1 Non specified
Vaccination	63/503 ^b	12,5%	26 Pain at inoculation point 23 Inflammation at inoculation point 38 Apathy 14 Hipertermia 16 Mild anaphylactic reaction 8 Severe anaphylactic reaction 2 Soft stool
Leisguard®	4/276 ^a	1,5%	1 False pregnancy 1 Galactorrea 3 Soft stool

Study of the effectiveness and safety of various strategies to prevent canine leishmaniosis : retrospective, multi centric study with 1.695 cases (2012-2016)

2. HIGHER PREVENTIVE EFFECTIVENESS

- > 80% using only LEISGUARD®⁴
- Close to 100% LEISGUARD + REPELLENTS^{2,3}

3. THE PREVENTION PROGRAMME IS MORE COST EFFECTIVE

- 1 60 ml bottle of LEISGUARD® protects a 10kg dog for 1 year.
- 1 pack of LEISGUARD® (2x60 ml) protects a 20kg dog for 1 year.

6

TRAVELLING DOGS

Adapting the prevention

The dogs that travel from Northern Europe and non endemic areas of Spain, usually travel to Leishmania endemic areas during holiday season (Easter, Summer, Christmas...).

LEISGUARD® in travelling dogs - Benefits:

1. QUICK PROTECTION: The preventive treatment using LEISGUARD® can be started prior to the trip or on the arrival in the endemic area.

The immunomodulation effect is evident 2 days after starting the treatment.⁷

INTERNATIONAL SCIVAC CONGRESS
CANINE LEISHMANIOSIS AND
OTHER VECTOR-BORNE DISEASES:
OUR CURRENT STATE OF
KNOWLEDGE
MARCH 8TH - 10TH 2013 - PISA - ITALY

Quick stimulating
effect of Leisguard®
on the dog's innate
immune system



2. PREVENTION PROTOCOL:
We recommend treating with **LEISGUARD® for 30 consecutive days** even if the stay in the endemic area is shorter.¹

7

SAFETY: based on evidence

After 4 years in the market and more than 500.000 dogs treated^c, LEISGUARD[®] is proven to be safer than other preventive options.

Side effects during commercial use (Around 500.000 of 30 consecutive days treatments)^b

Rare
($>1/10.000$ a $< 1/1.000$)

Mammal gland disorders (Gynecomastia, galactorrea) Apathy, gastrointestinal symptoms (abdominal pain, diarrhea, anorexia)

Very rare
($<1/10.000$ animals)

Behavioral disorders
(related to false pregnancy)

Based on the official available information^{a,b,c}, after recurrent or extended use of LEISGUARD[®] in dogs, no connection to any immune mediated disorder has been observed.

References:

- a.** Dossier de registro LEISGUARD[®] 5 mg/ml suspensión oral para perros
- b.** Ficha técnica LEISGUARD[®] 5 mg/ml suspensión oral para perros. <http://www.aemps.gob.es>
- c.** Comercialización LEISGUARD[®] (Enero 2.012 hasta la fecha de publicación de este material)
- d.** Esta información cumple con lo estipulado en el artículo 66 i) del RD 1246/2008

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COMPATIBLE and...

COMPATIBLE WITH OTHER PREVENTIVE STRATEGIES:

LEISGUARD® administration is compatible and complementary to other preventive options.^{2,3}

- Only repellents
- Vaccination
- Vaccination + repellents
- Leisguard®
- Leisguard® + repellents
- Leisguard® + vaccination + repellent

Data based on preventive strategies available on the market until May 2016



“The administration of LEISGUARD® combined with sand flies repellents is a much more effective preventive strategy than the use of repellents only, and significantly more effective and safe than vaccination, even if vaccine is associated to the use of repellents”.^{2,3}

9

...has NO INTERFERENCES

DOES NOT INTERFERE WITH DIAGNOSIS:

LEISGUARD® is different from vaccines: it boosts the immune response but does not increase antibodies levels so that an early diagnosis and a follow up with no interferences are a reality.



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PREVENTION WITH A GUARANTEE

leiSpro[®] PROGRAMME

THE REAL CONTROL OF LEISHMANIOSIS in the hands of the Veterinary Surgeon



Programa leiSpro[®]
El auténtico control de la Leishmaniosis

COPIA PARA ARCHIVO POR EL CLÍNICO VETERINARIO

Datos del perro Nº de control: 00001

Nombre:	Raza:
Nº Microchip:	Sexo:
Fecha nacimiento:	C. Postal: Viaje ¹ : Habitación ² :
Fecha inicio Programa:	Serología leiSguard ³ : Fecha: Resultado:

1) Eficaz frente a E. de sandía. 2) Postal extranjero.
3) El programa incluye la prueba de serología (Sandía, P. Hirsuti, S. cuticular, Cutibac).
ML: No storage

- ✓ Preliminar serological test (must be negative).
- ✓ Administer LEISGUARD[®] in June and October (30 days).

- ✓ Sand flies repellent (May-October).
- ✓ The Vet sets the Guarantee

Bibliography

1. SPC Leisguard
2. Homedes J, Sabaté D, Salichs M, Mayós I, Mateu C, Cristobal J, Martínez A, Bañeres A, Favarolo G, Oliveira A. Eficacia y seguridad de diferentes estrategias de prevención frente a la leishmaniosis canina: Estudio multicéntrico retrospectivo con 1077 casos (2012-2014). Póster SEVC 2014.
3. Homedes J, Salichs M, García G, Mateu C, Cristobal J, Martínez A, Bañeres A, Favarolo G, Oliveira A. Eficacia y seguridad de diferentes estrategias de prevención frente a la leishmaniosis canina: Estudio multicéntrico retrospectivo con 1695 casos (2012-2016). Póster SEVC 2016.
4. Sabaté D, Llinás J, Homedes, Sust M, Ferrer LI. A single-centre, open-label, controlled, randomized clinical trial to assess the preventive efficacy of a domperidone-based treatment programme against clinical canine leishmaniasis in a high prevalence area. Preventive Veterinary Medicine 115 (2014) 56-63.
5. Miranda S, Roura X, Picado A, Ferrer LI, Ramis A. Characterization of sex, age, and breed for a population of canine leishmaniosis diseased dogs. Research in Veterinary Science 85 (2008) 35-38.
6. Salichs M, Sabaté D, Rodón J, Homedes J. Estudio del efecto de Leisguard[®] sobre la eficacia de un plan vacunal estándar en cachorros. Póster SEVC-47º Congreso Nacional AVEPA, Oct 2012.
7. Sabaté D, Mayós I, Cepeda E, Homedes J. Rapid Stimulatory Effect of Leisguard[®] on the Canine Innate Immune System. Comunicación libre International SCIVAC Congress Canine Leishmaniosis and other vector-borne diseases. March 8-10th 2013, Pisa (Italy).
8. Tabar MD. Seguimiento de la infección de leishmaniosis en una área endémica un año después de la aplicación de nuevas medidas preventivas. Póster SEVC 2013.
9. Internal Report CIB-EV-05/03-SN

LEISGUARD[®] 5mg / ml oral suspension for dogs. **Composition:** domperidone: 5mg / ml. **Indications for use:** Prevention and control of the progression of canine leishmaniasis in the early stages of the disease (dogs with a low or moderate antibody titer and mild clinical signs such as peripheral lymphadenopathy or papillary dermatitis). Dosage and administration route: 0.5 mg / kg / day, equivalent to 1 ml of Leisguard / 10 kg of body weight, once a day, for 4 consecutive weeks. **Contraindications:** Do not use when the stimulation of gastric motility could be dangerous, for example, in case of gastrointestinal hemorrhage, mechanical obstruction or digestive perforation. Do not use in animals with known hypersensitivity to domperidone or to any excipient. Do not use in animals with a pituitary tumor secreting prolactin. Since domperidone is metabolized in the liver, it should not be administered to patients with hepatic impairment. **Special precautions for use in animals:** The administration of this veterinarian produces a transient elevation of plasma prolactin that could induce endocrine alterations such as galactorrhea. Therefore, it should be used with caution in animals prior to pseudopregnancy. No Registration: 2383 ESP. Entity holder of the marketing authorization: Ecuphar Veterinaria S.L.U. Avenida Río de Janeiro, 60 - 66, plant 13 08016 Barcelona (Spain)