

RECOMBITEK® Lyme.



All the Lyme disease protection dogs need and none of the antigens they don't.

Lyme disease is a growing threat to dogs.¹

Lyme disease bacteria (*Borrelia burgdorferi*) acquired from infected ticks may damage canine joints, kidneys and other tissues. Infection can persist despite aggressive antibiotic therapy. Areas of greatest incidence include the Atlantic seaboard, upper Midwest and Pacific coast,² but Lyme-positive dogs have been reported in all 50 states.³

AAHA recommends ...

RECOMBITEK Lyme is recommended for dogs with a known risk of exposure due to living in or visiting regions where risk of vector tick exposure is considered to be high, or where disease is known to be endemic.⁴



Advanced recombinant technology targets disease prevention.

RECOMBITEK Lyme:

- Delivers Outer surface protein A (OspA), the only antigen needed to stimulate immunity against Lyme disease in North America⁵⁻⁷
- Contains OspA in a nonadjuvanted formulation, unlike any other Lyme vaccine
- Reduces the potential risks of allergic and injection site reactions from unnecessary proteins and adjuvants
- Blocks infection before transmission can occur⁵
- Provides long-lasting, proven one-year duration of immunity⁶

100% of dogs protected.

In this study involving severe natural challenge, RECOMBITEK Lyme vaccine blocked infection before transmission could occur.

- 0% of vaccinated dogs became infected
- 100% of unvaccinated control dogs became infected

Results confirmed by culture, PCR, serology and xenodiagnosis.⁵

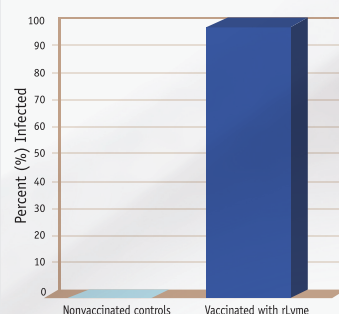
One-year duration of immunity.

With this live-tick challenge 366 days after vaccination, RECOMBITEK Lyme was proven to provide one-year duration of immunity.

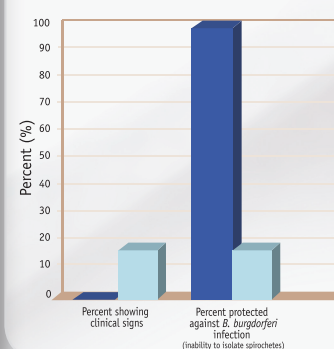
- 100% of vaccinated dogs tested negative for Lyme disease
- 82% of control dogs tested positive for Lyme disease

None of the vaccinated dogs exhibited clinical signs after challenge.⁶

100% of dogs protected from infection
(as determined by isolation of *B. burgdorferi* after challenge).⁵



Outstanding efficacy in a live-tick challenge 12 months post-vaccination.⁶



■ RECOMBITEK Lyme
■ Controls

No vaccinates showed any sign of infection either in a live tick challenge or controlled infection study

Because of this ...	You and your patients benefit this way ...
Targeted use of Outer surface protein A (OspA)	Dogs only receive exactly what's needed for protection ⁵⁻⁷
No unnecessary proteins or adjuvants	Reduced potential risk of reactions due to extraneous proteins and adjuvants
Blocks infection before transmission can occur ⁵	Reliable protection
100% of dogs protected from infection ⁵	Confidence in protecting your patients
12-month duration of immunity ⁶	Long-lasting immunity provides for annual revaccination

Canine Guarantee

Merial is committed to supporting our canine vaccines. To this end, we will provide support in the rare event of a suspected adverse event (AE) or perceived lack of efficacy (LOE) associated with one of our vaccines.

Leptospirosis:

If a dog is found to be positive* for leptospirosis after being fully vaccinated for the corresponding serovar (receiving a full course of initial vaccines plus annual boosters as required) Merial will support diagnosis and treatment up to a maximum of \$2,500. Dogs that did not complete a full course of vaccines, or test inconclusive, will qualify for support (amount to be determined on a case-by-case basis) depending on the vaccination history of the dog.

*positive as determined by the criteria outlined under the "terms and conditions"

Lyme:

In the event that a dog is found to be Lyme positive after being properly vaccinated with RECOMBITEK® Lyme, Merial will support testing with either the Cornell Canine Lyme Multiplex Assay or the IDEXX Quantitative C6 Antibody Test (please contact VTS to set up support for testing preemptively). If a positive diagnosis is confirmed, Merial will support urinalysis testing and treatment with appropriate antibiotics, such as amoxicillin or doxycycline. More in-depth support will be considered for testing and treatment of definitively diagnosed complications of Lyme disease on a case-by-case basis.

Canine Core:

Merial has multiple types of support for the antigens in our core vaccines (C3, C4, C6 combos). In the event of a suspected LOE or adverse event, please contact our VTS group and they will assist you in determining the appropriate support.

RECOMBITEK Lyme helps protect your patients whenever ticks attack.

RECOMBITEK Lyme product label description.⁸

RECOMBITEK Lyme is a liquid suspension of inactivated, purified Outer surface protein A (OspA) of *Borrelia burgdorferi* derived from a bacterial recombinant vector. It is packaged in 1 mL (1-dose) x 20-vial trays and in 1 mL (1-dose) x 50-vial trays.

Indications.

RECOMBITEK Lyme is recommended for vaccination of healthy dogs 9 weeks of age and older as an aid in the prevention of disease caused by *Borrelia burgdorferi*.

Dosage and administration.

Aseptically inject 1 mL (1 dose) subcutaneously into healthy dogs. For primary vaccination, revaccinate with a second 1 mL dose two to three weeks later. Revaccinate annually with a single 1 mL dose.

Storage.

Store at 35°F to 45°F (2°C to 7°C). Do not freeze.

Precautions.

Do not use chemicals to sterilize syringes and needles. Contains gentamicin as a preservative. In rare instances, administration of vaccines may cause lethargy, fever, and inflammatory or hypersensitivity types of reactions. Treatment may include antihistamines, anti-inflammatories and/or epinephrine.



To learn more about RECOMBITEK vaccines and how they can benefit your patients, contact your Merial Sales Representative or your Merial Distributor Representative or Call Merial Customer Care: 1-888-Merial-1 or Visit MERIALconnect.comSM

Ask your Merial Representative about our Satisfaction Guarantee on RECOMBITEK.

¹ Lyme disease. Available at: http://www.dogsandticks.com/diseases_and_symptoms/lyme_disease.php. Accessed November 20, 2014.

² The Merck Veterinary Manual website. Overview of Lyme borreliosis. Available at: http://www.merckmanuals.com/vet/generalized_conditions/lyme_borreliosis/overview_of_lyme_borreliosis.html?qt=lyme&alt=sh. Accessed November 20, 2014.

³ Parasites Prevalence Maps. U.S. Canine Positive Lyme Results. CAPC website: <http://www.cpcvet.org/parasite-prevalence-maps/>. Accessed November 12, 2014.

⁴ Welborn LV, DeVries JG, et al. Report of the American Animal Hospital Association (AAHA) Canine Vaccine Task Force: 2011 AAHA Canine Vaccine Guidelines, revised. Available at: <https://www.aahanet.org/publicdocuments/caninevaccineguidelines.pdf>. Accessed November 11, 2014.

⁵ Conlon JA, et al. Efficacy of a nonadjuvanted, outer surface protein A, recombinant vaccine in dogs after challenge by ticks naturally infected with *Borrelia burgdorferi*. *Veterinary Therapeutics* 2000;1:96-107.

⁶ Wikle RE, et al. Canine Lyme disease: One-year duration of immunity elicited with a canine OspA monovalent Lyme vaccine. *Intern J Appl Res Vet Med* 2006;4(1):23-28.

⁷ Chang Y, et al. Recombinant OspA protects dogs against infection and disease caused by *Borrelia burgdorferi*. *Infection and Immunity* 1995;63(9):3543-3549.

⁸ RECOMBITEK Lyme product label.



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