2 critical indications

1. SHEDDING: defense against urinary shedding caused by 4 key Leptospira serovars

Prevented leptospiuria in all vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>L. canicola</th>
<th>L. hardjo</th>
<th>L. icterohaemorrhagiae</th>
<th>L. pomona</th>
<th>L. canicola &amp;</th>
<th>L. icterohaemorrhagiae &amp;</th>
<th>L. canicola &amp; L. icterohaemorrhagiae</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active (n=12)</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Control (n=24)</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

A key objective of vaccination is to prevent urinary shedding of leptospires, which has potential zoonotic risks.

• 100% of dogs vaccinated with Nobivac® Canine 1-DAPPv+L4 developed leptospiruria
• 0% of dogs vaccinated with Nobivac® Canine 1-DAPPv+L4 developed leptospiruria
• All of the control dogs challenged with L. canicola and L. icterohaemorrhagiae developed leptospiruria
• 0% of dogs that developed leptospiruria

Protection for any dog

Nobivac® offers a range of core vaccine options, as well as unique non-core vaccine options, so you can build the right protocols for your patients

Prevention to the power of 2... That's Protection
Facts about Leptospirosis and Lyme Disease

• About 50 million US households own dogs—an estimated 78 million canine pets1,2
  – Only about half of household dogs are protected from parasitic diseases2
  – 56% of potential dog owners also have children3
• Reported cases of zoonotic diseases are on the rise, and are expected to continue to rise2,4-8
  – One out of every 16 dogs tests positive for Lyme disease, and the incidence is growing4,5
  – The CDC reports more than 30,000 cases of human Lyme disease annually, up from 19,931 in 20064,5
  – The prevalence of canine leptospirosis has increased in recent years, and as many as 8.2% of dogs are shedding leptospires, some asymptomatically8
  – Weather changes, population growth, and habitat encroachment have all increased human and canine exposure to pathogens and their carriers2,8,10

Leptospirosis presents multiple threats to your patients

Dogs at risk

Dogs at greatest risk for developing leptospirosis include those with:

• Access to ponds, lakes, streams, or standing water
• Exposure to urine from other infected animals, including:
  – Other dogs in crowded shelters or other pet care facilities
  – Wildlife (eg, rodents, raccoons, opossum, deer), either through direct contact with urine or through indirect contact with urine-contaminated water

Morbidity threats

As leptospirosis progresses, it can result in8,11:

• Leptospiromia
  – Leptospires can multiply in the bloodstream and spread to many tissues and organs
• Vascular damage/thrombocytopenia
  – Can lead to coagulopathy, hepatic failure, and renal failure

• Severe kidney and liver damage
  – Acute renal failure occurs in 40%-60% of dogs with severe clinical signs4
  – Acute hepatic failure or chronic hepatitis have been caused by specific serovars

Spreading disease

• Leptospiromia
  – Infected dogs can enter a carrier state
  – Organisms may persist in the kidney and be shed in the urine for weeks to months

OTHER DOGS MAY BECOME INFECTED
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  - Leptospiremia
    - Leptospires can multiply in the bloodstream and spread to many tissues and organs
  - Vascular damage/thrombocytopenia
    - Can lead to kidney, liver, and other organ failure
    - Contributes to coagulatory abnormalities and hemorrhages
  - Severe kidney and liver damage
  - Acute renal failure occurs in 40%-60% of dogs with severe clinical signs
  - Acute hepatic failure or chronic hepatitis have been caused by specific serovars

Spreading disease
- Leptospiruria8
  - Infected dogs can enter a carrier state
  - Organisms may persist in the kidney and be shed in the urine for weeks to months

OTHER DOGS MAY BECOME INFECTED
Nobivac®: Canine 1-DAPPv+L4
Bordetella
Canine Influenza Virus
Non-adjuvanted

1. SHEDDING:
Leptospira serovars
• L. pomona
• L. icterohaemorrhagiae
• L. canicola
• L. grippotyphosa

Nobivac Lepto4 prevents leptospiruria associated with
100% of dogs that developed leptospiruria

2 critical indications

Protection

SHARED Vaccinates

L. icterohaemorrhagiae
0% (n=12)
L. pomona
50% (n=12)
L. canicola
100%
L. grippotyphosa
60%

1-866-437-7955
Vaccine Protocol Help Line
(Monday – Friday, 8:30 AM – 5:00 PM EST)

18, 2013.

References:


2. MORTALITY: the only leptospirosis vaccine indicated to aid in the prevention of disease and mortality

- Protection for dogs facing the most severe challenges

Prevented mortality caused by 4 virulent *Leptospira* serovars\(^1\)\(^2\)

<table>
<thead>
<tr>
<th>Serovar</th>
<th>Vaccinates (n)</th>
<th>Controls (n)</th>
<th>% of dogs that died or required euthanasia 3-6 days after challenge</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>L. canicola</em></td>
<td>0% (n=20)</td>
<td>70% (n=10)</td>
<td>(P=0.0001)</td>
</tr>
<tr>
<td><em>L. grippotyphosa</em></td>
<td>0% (n=20)</td>
<td>40% (n=10)</td>
<td>(P=0.0077)</td>
</tr>
<tr>
<td><em>L. icterohaemorrhagiae</em></td>
<td>0% (n=20)</td>
<td>60% (n=10)</td>
<td>(P=0.0004)</td>
</tr>
<tr>
<td><em>L. pomona</em></td>
<td>0% (n=21)</td>
<td>44% (n=9)</td>
<td>(P=0.0046)</td>
</tr>
</tbody>
</table>

- No dogs vaccinated with Nobivac\(^\circ\) Canine 1-DAPPv+L\(_4\) died or required euthanasia
- 54% mortality and euthanasia in control groups, reflecting the severity of challenge

Clinical efficacy results showed that Nobivac Canine 1-DAPPv+L\(_4\) also prevented\(^1\)\(^2\)

- Leptospiremia
  - More than 85% of vaccinates had no leptospiremia; leptospires were cleared quickly from the blood in those that did
  - By contrast, all control dogs had leptospiremia, and it lasted significantly longer, by days
- Liver dysfunction
  - Serum levels of bilirubin and AST\(^*\) remained at normal levels in significantly more vaccinates
- Thrombocytopenia
  - Platelet counts remained in the normal range

\(^*\)AST = aspartate aminotransferase.
Nobivac® Lepto₄—Protection

Unmatched protection¹²
Nobivac Lepto₄ is the clear choice when compared with other 4-way leptospirosis vaccines.

A strategic advance: VacciPure™ filtration technology¹²
To promote an even higher level of vaccine quality, Merck Animal Health has introduced the special VacciPure filtration process in manufacturing Nobivac Lepto₄ and Nobivac® Canine 1-DAPPv+L₄.

Reduced total proteins through VacciPure¹²

Comparison of total protein in leptospirosis vaccines¹²

Gel electrophoresis demonstrates comparative purity of Nobivac® vaccines¹²

Results of a 749-dog field safety study¹²:
- Well tolerated on subcutaneous administration
  - Most adverse events involved scratching or small swellings at the injection site or lethargy, and were of short duration
  - Less frequently, soreness or vomiting occurred, but resolved within 24 hours
- Proven safe across a variety of breeds and ages

• Fewer total proteins (TP) means a more purified final product, which may reduce unwanted immune system responses, such as vaccine reactions¹²

Aids in the prevention of leptospirosis caused by...

<table>
<thead>
<tr>
<th>Prevention/Aids in</th>
<th>Nobivac® Lepto₄</th>
<th>VANGUARD® L₄</th>
<th>RECOMBITEK® 4 Lepto</th>
<th>ULTRA™ Duramune® 4L</th>
<th>LEPTOVAX® 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leptospira canicola</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>L. grippopyphosa</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td>L. icterohaemorrhagiae</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td>L. pomona</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

Products are registered trademarks of their respective owners.

Nobivac Lepto₄ is the clear choice when compared with other 4-way leptospirosis vaccines.

• A porous filtration membrane selectively removes extraneous proteins, salts, and solvents
• The outcome—fewer total proteins and a more purified final product

Aids in the prevention of mortality caused by virulent Leptospira serovars

Nobivac® Lepto₄—Protection

Nobivac® Canine 1-DAPPv+L₄; TP = 6.05 mg/mL
Nobivac Lepto₄; TP = 1.66 mg/mL
Ultra™ Duramune® 4L; TP = 11.01 mg/mL
Ultra™ Duramune® 4L; TP = 1.12 mg/mL

Comparison of total protein in leptospirosis vaccines¹²

Gel electrophoresis demonstrates comparative purity of Nobivac® vaccines¹²

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- Proven safe across a variety of breeds and ages

Products are registered trademarks of their respective owners.
A porous filtration membrane selectively removes extraneous proteins, salts, and solvents.

- The outcome—fewer total proteins and a more purified final product.

Unmatched protection

Nobivac Lepto<sub>4</sub> is the clear choice when compared with other 4-way leptospirosis vaccines.

Comparison of total protein in leptospirosis vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Total Protein (mg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nobivac® Lepto&lt;sub&gt;4&lt;/sub&gt;</td>
<td>1.7</td>
</tr>
<tr>
<td>VANGUARD&lt;sup&gt;®&lt;/sup&gt; L4</td>
<td>3.4</td>
</tr>
<tr>
<td>RECOMBITEK&lt;sup&gt;®&lt;/sup&gt; 4 Lepto</td>
<td>1.5</td>
</tr>
<tr>
<td>LEPTOVAX&lt;sup&gt;®&lt;/sup&gt; 4</td>
<td>2.5</td>
</tr>
</tbody>
</table>

New VacciPure filtration reduces total proteins

- Fewer total proteins (TP) means a more purified final product, which may reduce unwanted immune system responses, such as vaccine reactions.

A strategic advance: VacciPure<sup>™</sup> filtration technology

To promote an even higher level of vaccine quality, Merck Animal Health has introduced the special VacciPure filtration process in manufacturing Nobivac Lepto<sub>4</sub> and Nobivac® Canine 1-DAPPv+L<sub>4</sub>.

Videos

Gel electrophoresis demonstrates comparative purity of Nobivac<sup>®</sup> vaccines

Products are registered trademarks of their respective owners.
Incidence and risk of Lyme disease is on the rise

- Approximately 75% of unvaccinated dogs in endemic areas will eventually test positive for Lyme disease.13
- Canine Lyme disease vaccine doses have decreased by 3% since 2010.12
  - In 2013 only 3.4 million doses of Lyme vaccine were given, among a total of 49 million canine vaccinations.12

Get tough on canine Lyme with a 1-2 punch

OspC plays a pivotal role in Lyme disease transmission.

Nobivac Lyme is the vaccine with a traditional isolate targeted at OspA and a unique isolate proven to induce high levels of borreliacidal antibodies to OspC independent of the strain.12

The unique dual action behind the 1-2 punch—why Nobivac Lyme is so effective

1. Targets OspA in the tick’s midgut14,15

When an unfed Borrelia-infected tick attaches to a dog, high levels of OspA are expressed by the Borrelia residing in the tick’s midgut.

2. Targets OspC in the tick’s salivary glands and in the dog14,15

Soon after the tick begins its bloodmeal, OspA expression decreases and OspC expression increases, becoming the dominant Osp. Infection occurs when the Borrelia, which are now expressing only OspC, pass from the tick’s midgut to its salivary glands and then into the dog.13

The level of OspC borreliacidal antibodies was identified by a flow cytometric procedure that detects the response by monitoring increased fluorescence intensity. The change in mean fluorescence intensity in serum from vaccinated dogs was measured and compared with control serum from a healthy, nonvaccinated dog to determine OspC antibody response.

The borreliacidal antibodies in Nobivac Lyme were shown to be highly effective in killing B. burgdorferi and preventing infection.14

Nobivac Lyme is proven to aid in the prevention of subclinical arthritis in addition to clinical disease.14

The presence of nonviable organisms was also confirmed by darkfield microscopy.

Nobivac Lyme induces high levels of borreliacidal antibodies against OspC independent of the strain.14

落ちたドッグ症の予防に効果的

ノビワクレームは、OspAに対する一般的な接種に加えて、特定のOspCに対する効果的な予防剤であることを示しています。14

ノビワクレームでは、非活動的な細胞に対しても、OspCに対する効果的な予防剤が検出されている。14

The tick challenge study was a placebo-controlled trial involving thirty 8-week-old puppies. Dogs were challenged 44 days following first vaccination.

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**Powerful comparative benefits and proven safety**

<table>
<thead>
<tr>
<th>Nobivac® Lyme</th>
<th>LymeVax®</th>
<th>RECOMBITEK® Lyme</th>
<th>Duramune® Lyme</th>
<th>Vanguard® crLyme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induces OspA borreliacidal antibodies</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Induces OspC borreliacidal antibodies</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aids in the prevention of clinical disease caused by <em>Borrelia burgdorferi</em></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Aids in the prevention of subclinical arthritis associated with <em>B. burgdorferi</em></td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subcutaneous administration</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Initial vaccination</td>
<td>8 weeks</td>
<td>9 weeks</td>
<td>9 weeks</td>
<td>9 weeks</td>
</tr>
<tr>
<td>Second dose</td>
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<td>2-3 weeks</td>
<td>2-3 weeks</td>
<td>2-3 weeks</td>
</tr>
<tr>
<td>Annual vaccination recommended</td>
<td>1 year</td>
<td>1 year</td>
<td>1 year</td>
<td>1 year</td>
</tr>
</tbody>
</table>

**An exceptional safety profile you can rely on**

- Proven safe and well tolerated in a field safety trial of more than 600 dogs – 99.3% reaction-free
- Since 2009, Nobivac Lyme has been safely administered to over 4 million dogs

**Additional steps for the pet owner**

- Check pets daily for ticks, especially after time spent outdoors
- Remove ticks right away with appropriate methods
- Make a “tick check” part of every veterinary visit
- Discuss geographic incidence of tickborne diseases with the veterinarian
- Reduce the tick habitat on your property
- In case of heavy outdoor tick infestation, treat the yard with acaricides licensed for outdoor use; this may also be best left to pest control professionals
- In case of indoor tick infestation, get help from pest control professionals
- Prevent tick infestations by regularly treating dogs all year long with effective acaricides

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Nobivac® Lyme—Protection

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<td>2-4 weeks</td>
<td>2-3 weeks</td>
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Advanced vaccines to protect extraordinary bonds...

That’s Protection

**Nobivac® Lepto** and Nobivac® Canine 1-DAPPv+L₄

*Because life is precious*

- The canine leptospirosis vaccines with 2 critical indications
  - Prevents or aids in the prevention of urinary shedding
  - Aids in the prevention of mortality
- Proven safe and well tolerated in many breeds including small breeds
- Featuring an even higher level of quality due to VacciPure™ filtration

**Nobivac® Lyme**

*A powerful weapon against Lyme disease*

- The vaccine that induces 2 borreliacidal antibodies against
  - OspA in the tick’s midgut
  - OspC in the tick’s salivary glands and in the dog independent of the borrelia strain
- Nobivac Lyme is proven to aid in the prevention of subclinical arthritis and other signs of Lyme disease
  - No joint inflammation, stiffness, or lameness was observed

Ask about the Merck Animal Health line of flea and tick products!
A key objective of vaccination is to prevent urinary shedding of leptospires, which has potential public health implications. Nobivac Lepto4 prevents leptospirosis associated with four key serovars: L. pomona, L. icterohaemorrhagiae, L. canicola, and L. grippotyphosa. Of the control dogs challenged with L. pomona and L. icterohaemorrhagiae, 50% of control dogs developed leptospiruria and 0% of dogs vaccinated with Nobivac® Canine 1-DAPPv+L4 developed leptospiruria. For L. canicola and L. grippotyphosa, 100% of dogs vaccinated with Nobivac® Canine 1-DAPPv+L4 and 0% of control dogs developed leptospiruria.
2 critical indications

1. SHEDDING: defense against urinary shedding caused by 4 key Leptospira serovars

Prevented leptospiuria in all vaccines®:

- L. canicola
- L. grippotyphosa
- L. icterohaemorrhagiae
- L. pomona

A key objective of vaccination is to prevent urinary shedding of leptospires, which has potential health implications for both dogs and humans. Nobivac® Lepto4 aids in the prevention of leptospiruria associated with these serovars.

Nobivac® Lepto4 prevents leptospiruria associated with:
- L. canicola
- L. grippotyphosa
- L. icterohaemorrhagiae
- L. pomona

74
67
53
40
28
15
10
7
4
2

All of the control dogs challenged with L. canicola and L. grippotyphosa developed leptospiruria and 80% of control dogs challenged with L. icterohaemorrhagiae and L. pomona developed leptospirosera. Nobivac® Lepto4 prevented leptospiruria in all vaccinates®.

References: