

# ZOETIS INC.

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## LEPTOFERM-5<sup>®</sup>

Zoetis

**Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin**

U.S. Vet. Lic. No.: 190

**Description:** LEPTOFERM-5<sup>®</sup> contains chemically inactivated whole cultures of the 5 *Leptospira* serovars listed above.

**Indications:** LEPTOFERM-5<sup>®</sup> is for vaccination of healthy swine and cattle as an aid in preventing leptospirosis caused by *Leptospira canicola*, *L. grippotyphosa*, *L. hardjo*, *L. icterohaemorrhagiae*, and *L. pomona*.

### Directions:

1. General Directions: Vaccination of healthy swine and cattle is recommended. Shake well. Aseptically administer 2 mL intramuscularly. In accordance with Beef Quality Assurance guidelines, this product should be administered in the muscular region of the neck.
2. Primary Vaccination: Administer a single 2-mL dose to healthy cattle. Healthy swine should receive 2 doses administered 3-6 weeks apart.
3. Revaccination: Annual revaccination with a single dose is recommended for both species.
4. Good animal husbandry and herd health management practices should be employed.

**Precaution(s):** Store at 2°-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

Use entire contents when first opened.

Sterilized syringes and needles should be used to administer this vaccine.

**Caution(s):** As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.

This product has been shown to be efficacious in healthy animals. A protective immune response may not be elicited if animals are incubating an infectious disease, are malnourished or parasitized, are stressed due to shipment or environmental conditions, are otherwise immunocompromised, or the vaccine is not administered in accordance with label directions.

**Warning(s):** Do not vaccinate within 21 days before slaughter.

For veterinary use only.

**Discussion:** Disease Description: Leptospirosis is a worldwide disease of animals and humans and causes serious economic loss to the livestock industry.<sup>1</sup> The disease is usually transmitted by direct or indirect contact with leptospire-infected urine.

Leptospirosis in swine is characterized by poor productivity, fever, anemia, kidney inflammation, and abortions; late-term abortions are the most important effect. In calves, clinical signs of leptospirosis may include fever, prostration, loss of appetite, shortness of breath, anemia, and blood in the urine. In adult cattle, the most common clinical sign is reproductive loss, including abortion and premature or full-term birth of weak calves. Decreased milk production may also occur.<sup>2</sup> *Leptospira* spp. are known zoonotic pathogens.

All the above *Leptospira* serovars produce identical clinical signs, yet immunity to leptospirosis is serovar-specific.<sup>1</sup> Vaccination against each serovar, therefore, is indicated for protection.

**Trial Data:** Safety and Efficacy: During developmental tests and in extensive field use of LEPTOFERM-5<sup>®</sup>, no significant postvaccination reactions were reported.

Although *L. hardjo* has been isolated from field cases of leptospirosis, attempts to experimentally induce clinical disease with that serovar had yielded unreliable results. Hence, no valid challenge-of-immunity tests on *L. hardjo* bacterin had been possible. Recent reports, however, have identified a method to induce clinical *L. hardjo* infection in cattle<sup>2</sup> and have also identified 2 distinct genotypes of *L. hardjo* in cattle.<sup>3,4</sup>

Accordingly, challenge-of-immunity tests were conducted to determine the efficacy of LEPTOFERM-5<sup>®</sup> against both *L. hardjo* genotypes.<sup>5</sup> Seventeen healthy heifers were divided into 2 groups of 6 vaccinates each and a group of 5 nonvaccinated controls. Vaccinates were administered the *L. hardjo* fraction of LEPTOFERM-5<sup>®</sup> in 1- or 2-dose regimens. Subsequently all cattle were challenged with disease-causing strains of both *L. hardjo*

genotypes. After challenge, leptospire were recovered from the urine of all controls, which continued shedding leptospire in the urine until necropsy at 31-49 days after challenge. Three controls (60%) also experienced fever and developed leptospire in the blood. Conversely, leptospire were not recovered from the urine or kidneys of any vaccinates, and leptospire were recovered from the blood of only 1 vaccinate (8%) for 1 day.

Thus, efficacy of the *L. hardjo* fraction against both genotypes in cattle was confirmed. These results are similar to results of previously conducted challenge-of-immunity tests on the other 4 fractions of LEPTOFERM-5<sup>®</sup> in both cattle and swine. In those studies also, vaccinated animals remained healthy after challenge, while nonvaccinated animals developed clinical signs of leptospirosis.

**References:** Available upon request.

75-4475-02

**Presentation:** 10 dose and 50 dose vials.

**NAC No.:** 3690057.2