Spirovac™ L5

Pfizer

Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin

PRODUCT DESCRIPTION: Spirovac L5 contains a specially prepared, inactivated and adjuvanted unique strain of Leptospira borgpetersenii serovar hardjo-bovis together with inactivated and adjuvanted cultures of L. pomona, L. grippotyphosa, L. canicola and L. icterohaemorrhagiae.

INDICATIONS: Spirovac L5 is for vaccination of healthy cattle, including pregnant cows and heifers, over 4 weeks of age, as an aid in preventing disease caused by the above organisms. In addition, it is especially recommended to prevent establishment of L. hardjo in the kidney, and thus shedding in the urine, for at least 12 months. Spirovac L5 also prevents the establishment of L. hardjo in the genital tract and aids in preventing infection of the fetus.

SAFETY: The safety of Spirovac L5 was demonstrated using the product combined with Campylobacter fetus (Spirovac VL5) in a field study in two separate states in the USA (Nebraska and Indiana) using a total of 396 beef and dairy cattle comprising 100 pregnant dairy cows, 103 pregnant beef cows, 73 calves at 12 weeks of age and a further 120 calves at 4 weeks of age.

Apart from one dairy cow that exhibited an apparent delayed hypersensitivity reaction several hours after vaccination, no other untoward systemic reactions attributable to Spirovac VL5 were encountered. Five animals showed swelling at the site of injection and did not require treatment.

EFFICACY: Researchers at the National Animal Disease Center (NADC) of the Agriculture Research Service (ARS), United States Department of Agriculture (USDA), Ames, IA, conducted 2 separate studies evaluating the efficacy of Pfizer’s Spirovac hardjo-bovis vaccine against the colonization of the urinary and reproductive tracts of cattle when challenged with virulent strains of L. borgpetersenii serovar hardjo-bovis.1,2 The NADC challenge strains used in these studies are reliable in their ability to cause urinary shedding and represent the most common field strains. In the first study, 8 heifers were vaccinated twice and challenged 16 weeks post second vaccination with serovar hardjo type hardjo-bovis A by intraperitoneal inoculation or conjunctival instillation for 3 consecutive days. Eight nonvaccinated heifers were similarly challenged. Urine samples were collected weekly. Heifers were euthanized 11–14 weeks post challenge and kidneys were examined for evidence of colonization. Leptospires were not detected in any of the urine or tissue samples from the Spirovac hardjo-bovis vaccinated heifers, whereas 6/8 nonvaccinated heifers shed leptospires in their urine and all 8 had evidence of renal colonization. In the second study, 12 Spirovac hardjo-bovis-vaccinated and 12 nonvaccinated heifers were challenged 18 weeks post vaccination by instillation of either serovar hardjo type hardjo-bovis A or type hardjo-bovis B into the conjunctival sac and vagina. Cattle were monitored to detect urinary shedding of serovar hardjo for 8 weeks after challenge. The presence of leptospires in the uterus and oviducts was determined at necropsy. Urinary shedding of serovar hardjo was not detected in any (0/12) of the cattle vaccinated with Spirovac hardjo-bovis vaccine. In contrast, nonvaccinated cattle became infected and shed serovar hardjo in their urine (12/12). Vaccinated cattle also were protected from leptospiral colonization of the reproductive tract, whereas leptospires were detected in the uterus or oviducts of 10/12 control heifers.

The efficacy of Pfizer’s Spirovac hardjo-bovis vaccine as an aid in preventing placental and fetal infection was established in a study conducted by researchers at the NADC and Michigan State University.3,4 Heifers were vaccinated two times prior to breeding and then challenged at mid-gestation with virulent L. borgpetersenii serovar hardjo by conjunctival and vaginal instillation. Heifers were monitored for urinary shedding until calving. Heifers, calves and cows were euthanized as soon as possible after parturition and urine samples, maternal kidney, placenta and fetal tissues were examined to detect the presence of leptospires. Urinary shedding of serovar hardjo was detected in all (8/8) nonvaccinated control heifers and in none (0/16) of the vaccinated heifers after challenge. Leptospires were detected in the placentas or fetal tissues of 5/8 control cattle, whereas leptospires were not detected in any of the placentas or fetal tissues of the 16 Spirovac hardjo-bovis-vaccinated heifers. Therefore, vaccination with Spirovac hardjo-bovis vaccine prevented fetal infection in heifers challenged at mid-gestation with L. borgpetersenii serovar hardjo.
To determine the efficacy of Pfizer’s Spirovac hardjo-bovis vaccine in young calves with maternally derived antibodies, a group of 12 calves from previously vaccinated cows were divided into 4 equal groups, with the first dose of vaccine given at either 4, 6, 10 or 18 weeks of age and the second dose given 4 weeks after the first dose according to label recommendations. Seven seronegative calves from unvaccinated cows were used as a control group. All calves were challenged at 30–32 weeks of age. Prevaccination microscopic agglutination titers (MAT) ranged from 2 to 25, with maternal antibody titers observed as long as 13 weeks after birth. MAT titers were significantly higher in controls than vaccinates post challenge. Serological titer rises in vaccinates were inversely proportional to prevaccination titers. Leptospiruria was not detected in any of the vaccinated calves but occurred in 71% of control calves within 21 days of challenge and in all controls by 35 days. This study showed that young calves vaccinated as early as 4 weeks of age were protected against a virulent challenge with L. borgpetersenii serovar hardjo-bovis.5

In a study conducted by researchers at the University of Massachusetts, NADC and Michigan State University,6 Pfizer’s Spirovac hardjo-bovis vaccine was demonstrated to induce a strong, sustained cell-mediated immune response against L. borgpetersenii serovar hardjo. Spirovac hardjo-bovis vaccine induced production of gamma interferon and strong antigen-specific proliferative responses by peripheral blood mononuclear cells beginning 2 months after the first dose of vaccine and continuing for the 7-month study period. These responses were absent from nonvaccinated control cattle. A cell-mediated immune response is associated with protection against L. borgpetersenii serovar hardjo.

DURATION OF IMMUNITY: Twelve months duration of immunity was shown in a 54-week vaccination-challenge study. Eighteen 7- to 10-month-old calves were divided into 2 groups. Nine calves were vaccinated twice with Pfizer’s Spirovac hardjo-bovis vaccine, according to label recommendations, at 4-week intervals while 9 calves were held as controls. The 18 calves were housed together, held in isolation for 54 weeks and subsequently challenged with L. borgpetersenii serovar hardjo-bovis. Spirovac hardjo-bovis vaccine was shown to protect 100% of the vaccinated calves against urinary shedding (leptospiruria). It was concluded that Spirovac hardjo-bovis vaccine could provide protection for at least 12 months when administered to healthy animals according to label recommendations.3

DIRECTIONS:

1. General Directions: Vaccination of healthy cattle, including pregnant cows and heifers, is recommended. Shake well. Aseptically administer 2 mL subcutaneously or intramuscularly high on the side of the neck.

2. Primary Vaccination: Healthy cattle should receive 2 doses administered 4–6 weeks apart with booster doses given as necessary. When used as an aid in preventing genital or fetal infection, booster doses should be completed at least 2 weeks prior to breeding. Primary vaccination with this product in calves from 4 weeks of age with a second dose 4–6 weeks later will prevent infection, colonization and subsequent shedding of serovar hardjo-bovis, a source of further infection in the herd.

3. Revaccination: Annual revaccination with a single dose is recommended. Include all bulls in programs of vaccination. As part of normal biosecurity procedures, all replacement animals should begin a two-dose course of vaccination upon arrival.

4. Good animal husbandry and herd health management practices should be employed.

PRECAUTIONS:

1. Store away from light at 2°–7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

2. Use entire contents when first opened.

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

4. Do not vaccinate within 21 days before slaughter.

5. As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and
should be followed with appropriate supportive therapy.

6. 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.

REFERENCES:


Technical inquiries should be directed to Pfizer Animal Health Veterinary Services, (800) 366–5288 (USA), (800) 461–0917 (Canada).

For veterinary use only.

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