

Bovine Rhinotracheitis-Respiratory Syncytial Virus Vaccine

Modified Live Virus

Leptospira Pomona Bacterin

Bovi-Shield® IBR-BRSV-LP

PRODUCT DESCRIPTION: Bovi-Shield IBR-BRSV-LP is for vaccination of healthy, nonpregnant cattle as an aid in preventing infectious bovine rhinotracheitis caused by infectious bovine rhinotracheitis (IBR) virus, disease caused by bovine respiratory syncytial virus (BRSV), and leptospirosis caused by *Leptospira pomona*. Bovi-Shield IBR-BRSV-LP may be administered to calves nursing pregnant cows provided their dams were vaccinated, according to label directions, with Bovi-Shield FPT™ 4+L5, Bovi-Shield FP 4+VL5 or PregGuard® FP 9 prior to breeding. Bovi-Shield IBR-BRSV-LP is a freeze-dried preparation of modified live virus (MLV) strains of IBR and BRSV viruses, plus a liquid bacterin containing *L. pomona*. The liquid bacterin is used to rehydrate the freeze-dried vaccine. Viral antigens are propagated on established cell lines.

DISEASE DESCRIPTION: IBR and BRSV viruses are commonly associated with respiratory disease and/or reproductive failure in cattle. IBR virus infection is characterized by high temperature, excessive nasal discharge, conjunctivitis and ocular discharge, inflamed nose ("red nose"), increased rate of respiration, coughing, loss of appetite, and depression. Cattle infected during pregnancy may abort.

BRSV is the etiologic agent of a specific viral respiratory disease of cattle of all ages, including nursing calves. Infection is characterized by rapid breathing, coughing, loss of appetite, discharge from the nose and eyes, fever, and swelling around the throat and neck. In an acute outbreak, deaths may follow within 48 hours after onset of signs. Clinically, BRSV infection may be indistinguishable from other viral infections associated with the bovine respiratory disease complex. BRSV infection facilitates invasion and replication of other respiratory pathogens. Exacerbation of clinical signs has been documented when concurrent BRSV and BVD or IBR infection exists.

Leptospirosis may be caused by several serovars of *Leptospira*, of which *L. pomona* is one of the most common affecting cattle. *Leptospira* localize in the kidneys, are shed in the urine, and cause anemia, bloody urine, fever, loss of appetite, and prostration in calves. Signs are usually subclinical in adult cattle. Infected pregnant cows, however, often abort, and dairy cows may exhibit a marked decrease in milk production. *Leptospira* spp. are known zoonotic pathogens.

SAFETY AND EFFICACY: In safety studies of the fractions of Bovi-Shield IBR-BRSV-LP, no adverse reactions to vaccination were observed.

Efficacy of each fraction of Bovi-Shield IBR-BRSV-LP was demonstrated in challenge-of-immunity studies. Cattle vaccinated with any fraction of Bovi-Shield IBR-BRSV-LP, followed by challenge with a disease-causing strain of that fraction, showed no signs or had significantly fewer clinical signs than nonvaccinated control cattle. Serologic studies demonstrated no immunologic interference among the fractions of Bovi-Shield IBR-BRSV-LP.

DIRECTIONS:

1. *General Directions:* Vaccination of healthy, nonpregnant cattle is recommended. Aseptically rehydrate the freeze-dried vaccine with the liquid bacterin provided, shake well, and 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, followed by a second dose of Bovi-Shield BRSV 3–4 weeks later.

3. *Revaccination:* Annual revaccination with a single dose is recommended.

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

PRECAUTIONS:

1. Do not use in pregnant cows (abortions can result). Do not use in calves nursing pregnant cows unless their dams were vaccinated, according to label directions, with Bovi-Shield FP 4+L5, Bovi-Shield FP 4+VL5 or PregGuard FP 9 prior to breeding.

2. Store at 2°–7°C. Prolonged exposure to higher temperatures and/or direct sunlight may adversely affect potency. Do not freeze.

3. Use entire contents when first opened.

4. Sterilized syringes and needles should be used to administer this vaccine. Do not sterilize with chemicals because traces of disinfectant may inactivate the vaccine.

5. Burn containers and all unused contents.

6. Do not vaccinate within 21 days before slaughter.

7. Contains gentamicin as preservative.

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

9. 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.

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

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