Bovine Respiratory Syncytial Virus Vaccine

Modified Live Virus

Bovi-Shield® BRSV

**PRODUCT DESCRIPTION:** Bovi-Shield BRSV is for vaccination of healthy cattle, including pregnant cows, as an aid in preventing disease caused by bovine respiratory syncytial virus (BRSV). Bovi-Shield BRSV is a freeze-dried preparation of an attenuated strain of BRSV propagated on an established bovine cell line, plus a sterile diluent used to rehydrate the freeze-dried vaccine.

**DISEASE DESCRIPTION:** 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. Pathology typically consists of subpleural and interstitial emphysema with consolidating lesions characteristic of pneumonia. Clinically, BRSV infection may be indistinguishable from other viral infections associated with the bovine respiratory disease complex. Exacerbation of clinical signs has been documented when concurrent BRSV and BVD or IBD infection exists.

**SAFETY AND EFFICACY:** Safety of Bovi-Shield BRSV was demonstrated by controlled testing in a comprehensive cross-section of over 28,000 healthy cattle under a variety of typical field conditions. Test animals included calves ranging in age from 1–4 months old, bull calves ranging in age from 5–9 months old, feeder cattle ranging in weight from 500–900 lb, dairy cows, and over 1,000 pregnant cows in all trimesters of pregnancy. Bovi-Shield BRSV was administered to test animals in two 2-mL, intramuscular doses given 4 weeks apart, and the cattle were then observed over a 14-day period following each dose. The overall abortion rate for vaccinated pregnant cows was no greater than the generally referenced spontaneous abortion rate. At conclusion of the studies, participating veterinarians reported no local or systemic adverse reactions related to use of the vaccine. Efficacy of Bovi-Shield BRSV was demonstrated in challenge-of-immunity tests conducted under federally approved protocol. All vaccinated cattle remained clinically normal following challenge which produced typical signs of disease in nonvaccinated control cattle.

**DIRECTIONS:**

**General Directions:** Vaccination of healthy cattle, including pregnant cows, is recommended. Aspirally rehydrate the freeze-dried vaccine with the sterile diluent provided, shake well, and administer 2 mL subcutaneously or intramuscularly. In accordance with Beef Quality Assurance guidelines, this product should be administered SC or IM in the neck region.

**Primary Vaccination:** Administer a single 2-mL dose to healthy cattle. To avoid possible maternal antibody interference with active immunization, calves vaccinated before the age of 6 months should be revaccinated after 6 months of age.

**Secondary Vaccination:** Administer a single 2-mL dose to任何 cattle. To avoid possible maternal antibody interference with active immunization, calves vaccinated before the age of 6 months should be revaccinated after 6 months of age.

**Revaccination:** Annual revaccination with a single dose is recommended. Good animal husbandry and herd health management practices should be employed.

**PRECAUTIONS:**

- **Store at 2–8°C:** Prolonged exposure to higher temperatures and/or direct sunlight may adversely affect potency. Do not freeze.
- **Use entire contents when first opened.**
- **Sterilized syringes and needles should be used to administer this vaccine.** Do not sterilize with chemicals because traces of disinfectant may inactivate the vaccine.
- **Burn containers and all unused contents.**
- **Do not vaccinate within 21 days before slaughter.**
- **Contains gentamicin as preservative.**
- **As with many vaccines, anaphylaxis may occur after use.**
- **Initial antigen 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.

**REFERENCES:**

10. Technical inquiries should be directed to Zoetis Inc. Technical Services, (888) 963-8471 (USA), (800) 481-0917 (Canada).

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Zoetis

Zoetis Inc.

Kalamazoo, MI 49007, USA

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