BOVI-SHIELD® GOLD FP™ 5 VL5

Pfizer

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3-Respiratory Syncytial Virus Vaccine

Modified Live Virus

Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin

PRODUCT DESCRIPTION: Bovi-Shield GOLD FP 5 VL5 is for vaccination of healthy cows and heifers prior to breeding as an aid in preventing abortion caused by infectious bovine rhinotracheitis (IBR, bovine herpesvirus Type 1) virus; persistently infected calves caused by bovine virus diarrhea (BVD) Types 1 and 2; respiratory disease caused by IBR, BVD Types 1 and 2, parainfluenza3 (PI3) and bovine respiratory syncytial virus (BRSV); campylobacteriosis (vibriosis) caused by Campylobacter fetus; and leptospirosis caused by Leptospira canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae, and L. pomona. Bovi-Shield GOLD FP 5 VL5 may be administered to pregnant cattle provided they were vaccinated, according to label directions, with Bovi-Shield FP 4+L5, Bovi-Shield FP 4+VL5, Bovi-Shield GOLD FP 5 L5, Bovi-Shield GOLD FP 5 VL5, PregGuard® FP 9 or PregGuard GOLD FP 10 within the past 12 months. Bovi-Shield GOLD FP 5 VL5 may also be administered to calves nursing pregnant cows provided their dams were vaccinated within the past 12 months as described above. The freeze-dried vaccine is a preparation of modified live virus (MLV) strains of IBR, BVD (Types 1 and 2), PI3, and BRSV propagated on an established cell line. The Campylobacter fetus bacterin is an inactivated suspension of C. fetus. It is combined with an inactivated Leptospira bacterin prepared from whole cultures of the agents indicated. The Campylobacter-Leptospira bacterin is supplied as a diluent for the IBR-BVD-PI3-BRSV vaccine.

DISEASE DESCRIPTION: IBR, BVD, PI3, 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.

BVD virus may be transmitted in nasal secretions, saliva, blood, feces, and/or urine, and by direct contact with contaminated objects; it invades through the nose and mouth and replicates systemically. Infection during pregnancy may result in abortion, fetal resorption, or congenital malformation of the fetus. Moreover, if susceptible cows are infected with noncytopathic BVD virus during the first trimester of pregnancy, their calves may be born persistently infected with the virus. Exposure of those calves to certain virulent cytopathic BVD virus strains may precipitate BVD-mucosal disease. Both BVD Types 1 and 2 can show a variety of clinical signs. The signs may be mild and not readily apparent. Clinical signs may include severe immune suppression, diarrhea, anorexia, depression, fever and respiratory disease. If infected with some Type 2 strains of BVD, severe thrombocytopenia may occur and hemorrhaging may be seen.

PI3 virus usually localizes in the upper respiratory tract, causing elevated temperature and moderate nasal and ocular discharge. Although clinical signs typically are mild, PI3 infection weakens respiratory tissues. Invasion and replication of other pathogens, particularly Pasteurella spp., is thereby facilitated and may result in pneumonia.

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 swallowing 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, like PI3, facilitates invasion and replication of other respiratory pathogens. Exacerbation of clinical signs has been documented when concurrent BRSV and BVD or IBR infection exists.

Campylobacteriosis (vibriosis) is an insidious venereal disease of cattle. The Campylobacter organism infects the cow’s genital tract causing early embryonic death. The disease is characterized by infertility, repeat breeding, and a prolonged calving season.

Leptospirosis may be caused by several serovars of Leptospira, of which L. canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae, and L. pomona are 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: The cell lines on which the modified live virus fractions are produced have been extensively tested to ensure freedom from adventitious agents. Two studies were conducted demonstrating the safety of the BVD Type 2 fraction of Bovi-Shield GOLD FP 5 VL5. In the first study 14- to 15-month-old crossbred beef calves negative for BVD virus and BVD neutralizing antibodies, and with no history of BVD vaccination, were given a field dose of the BVD Type 2 strain intramuscularly. Susceptible contact control animals maintained in this study did not seroconvert to BVD. In the second study, 4- to 8-week-old, colostrum-deprived crossbred beef calves, negative for BVD virus and BVD neutralizing antibodies, were given a field dose of the BVD Type 2 strain intranasally. In both studies, no clinical signs attributable to BVD infection were observed, and attempts to re-isolate the vaccine virus from nasal secretions were unsuccessful.
The safety of the fractions of Bovi-Shield GOLD FP 5 VL5 was demonstrated in 3 field safety studies, each at different geographic locations, utilizing a total of 600 animals. Safety was evaluated in 6- to 8-month-old beef calves in a feedlot environment, in 3- to 7-month-old beef calves prior to weaning, and in 1- to 4-week-old dairy calves. No injection site, serious systemic or allergic reactions or clinical abnormalities attributable to vaccination were observed.

The effectiveness of the IBR and BVD fractions of Bovi-Shield GOLD FP 5 VL5 in preventing abortion caused by IBR and persistently infected calves caused by BVD (Types 1 & 2) was demonstrated in separate IBR, BVD Type 1, and BVD Type 2 challenge-of-immunity studies.

Efficacy of each fraction of Bovi-Shield GOLD FP 5 VL5 was demonstrated in challenge-of-immunity studies. Cattle vaccinated with any fraction of Bovi-Shield GOLD FP 5 VL5, 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 GOLD FP 5 VL5.

Three field studies demonstrated the safety of Bovi-Shield GOLD FP 5 VL5 when administered to pregnant cows previously vaccinated with one of the Bovi-Shield FP or PregGuard FP products. In all three studies, cows were vaccinated with either Bovi-Shield FP 4+L5 or PregGuard FP 9 between 12 and 17 months prior to vaccination with either Bovi-Shield GOLD FP 5 VL5 or placebo during the first, second, or third trimester of pregnancy. The pregnancy status of cows vaccinated during the first trimester of pregnancy was determined approximately 3 months postvaccination. Pregnancy was confirmed in 197 of 198 (99.5%) placebo-vaccinated cows and 198 of 200 (99%) cows vaccinated with Bovi-Shield GOLD FP 5 VL5.

Cows vaccinated during the second or third trimester of pregnancy were observed through calving, and the health status of their newborn calves was determined. Second trimester vaccination resulted in the delivery of healthy calves in 149 of 150 (99.3%) placebo vaccinates, and in 162 of 164 (98.8%) cows vaccinated with Bovi-Shield GOLD FP 5 VL5. One hundred percent of cows vaccinated with placebo (138 of 138) and Bovi-Shield (184 of 184) during the third trimester of pregnancy delivered healthy calves. The effectiveness of Bovi-Shield GOLD FP 5 VL5 in providing protection from a virulent BVD Type 2 challenge was demonstrated in 2- to 3-month-old, colostrum-deprived beef calves. Vaccinated calves, along with a group of nonvaccinated controls, were challenged intranasally with virulent, noncytopathic BVD Type 2 at 28 days postvaccination.

DIRECTIONS:
1. General Directions: Vaccination of healthy cattle is recommended. Aseptically rehydrate the freeze-dried vaccine (Bovi-Shield GOLD FP 5) with the liquid bacterin provided (Vibrio/Leptoferm-5™), 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 all breeding cows and heifers approximately 1 month prior to breeding or being added to the herd, followed by single doses of Vibrio/Leptoferm-5 and Bovi-Shield BRSV 3–4 weeks later.
3. Revaccination: Annual revaccination with a single dose of Bovi-Shield GOLD FP 5 VL5 is recommended.
4. Good animal husbandry and herd health management practices should be employed.

PRECAUTIONS:
1. Do not use in pregnant cows (abortion can result) unless they were vaccinated, according to label directions, with Bovi-Shield FP 4+L5, Bovi-Shield FP 4+VL5, Bovi-Shield GOLD FP 5 L5, Bovi-Shield GOLD FP 5 VL5, PregGuard FP 9 or PregGuard GOLD FP 10 within the past 12 months. Do not use in calves nursing pregnant cows unless their dams were vaccinated within the past 12 months as described above. Do not vaccinate neonatal calves.
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. Vaccination of stressed animals should be delayed.
9. Occasional hypersensitivity reactions may occur up to 18 hours postvaccination. Owners should be advised to observe animals during this period. While this event appears to be rare overall, dairy cattle may be affected more frequently than other cattle. Animals affected may display excessive salivation, incoordination, and/or dyspnea. Animals displaying such signs should be treated immediately with epinephrine or equivalent. In nonresponsive animals, other modes of treatment should be considered.
10. As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.
11. 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.

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