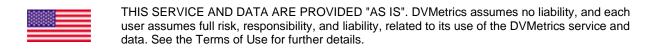
ZOETIS INC. 333 PORTAGE STREET. KALAMAZOO. MI. 49007

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Bovi-Shield GOLD® FP® 5 VL5

Zoetis

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

Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin This product has been shown to be effective for the vaccination of healthy cows and heifers prior to breeding against respiratory disease caused by infectious bovine rhinotracheitis (IBR, bovine herpesvirus Type 1) virus; bovine virus diarrhea (BVD) Type 1, including 1b, and Type 2 virus; parainfluenza3 (PI3) virus and bovine respiratory syncytial virus (BRSV); reproductive disease caused by IBR and BVD Type 1, including 1b, and Type 2; and disease caused by *Campylobacter fetus, Leptospira canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae*, and *L. pomona*. A duration of immunity of at least 12 months has been demonstrated against IBR-induced abortion and persistently infected calves caused by BVD virus Types 1 and 2. Duration of immunity against the remaining fractions has not been established. For more information regarding efficacy and safety data, go to productdata.aphis.usda.gov. This product has been shown to be effective against abortion due to IBR; persistently infected calves caused by BVD Type 1, including 1b, and Type 2; and testicular infection caused by BVD Type 2.

Bovi-Shield GOLD FP 5 VL5 may be administered to pregnant cattle provided they were vaccinated, according to label directions, with any Bovi-Shield GOLD FP or PregGuard[®] GOLD FP vaccine 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. To help ensure safety in pregnant cattle, heifers must receive at least 2 doses of any Bovi-Shield GOLD FP or PregGuard GOLD FP product with the second dose administered approximately 30 days prebreeding.

PRODUCT DESCRIPTION: The freeze-dried vaccine is a preparation of modified live virus (MLV) strains of IBR, BVD (Types 1 and 2), Pl₃, and BRSV. The *Campylobacter* 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-Pl₃-BRSV vaccine.

DIRECTIONS:

General Directions: Vaccination of healthy cattle is recommended. Aseptically rehydrate the freeze-dried vaccine with the liquid bacterin provided, mix 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.

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 a single dose of Vibrio/Leptoferm-5[®] 3-4 weeks later.

Revaccination: Historically, annual revaccination with this product was recommended. The need for booster vaccinations has not been established for this product; consultation with a veterinarian or the manufacturer is recommended.

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

PRECAUTIONS:

Do not use in pregnant cows (abortions can result) unless they were vaccinated, according to label directions, with any Bovi-Shield GOLD FP or PregGuard GOLD FP vaccine 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 calves under 3 months of age.

To help ensure safety in pregnant cattle, heifers must receive at least 2 doses of any Bovi-Shield GOLD FP or PregGuard GOLD FP product with the second dose administered approximately 30 days prebreeding. 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. Inactivate unused contents before disposal.

Do not vaccinate within 21 days before slaughter.

Fetal health risks associated with vaccination of pregnant animals with modified live vaccines cannot be unequivocally determined by clinical trials conducted for licensure. Management strategies based on vaccination of pregnant animals with modified live vaccines should be discussed with a veterinarian.

Vaccination of stressed animals should be delayed.

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.

Contains gentamicin and thimerosal as preservatives.

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

Do not mix with other products, except as specified above.

In case of human exposure, contact a physician.

Technical inquiries should be directed to Zoetis Inc. Veterinary Services, (888) 963-8471.

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.

For veterinary use only.

VLN 190/PCN 44B1.22

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Presentation: 10 and 50 dose vials. CPN: 3690208.11