ZOETIS INC.
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Bovi-Shield GOLD® FP® 5 L5 HB
Zoetis
Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza$_3$-Respiratory Syncytial Virus Vaccine
Modified Live Virus
Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin

This product has been shown to be effective for the vaccination of healthy cattle, including pregnant cows and heifers, 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, parainfluenza$_3$ (PI$_3$) virus and bovine respiratory syncytial virus (BRSV); reproductive disease caused by IBR, BVD Type 1, including 1b, and Type 2; and disease caused by *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, persistently infected calves caused by BVD virus Types 1 and 2, and renal infection due to *L. hardjo*. 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 and fetal infection caused by BVD Type 1, including 1b, and Type 2; testicular infection caused by BVD Type 2; fetal, genital, and renal infections, and leptospiuria caused by *L. hardjo bovis*.

Bovi-Shield GOLD FP 5 L5 HB 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 L5 HB 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 at least 30 days prebreeding.

PRODUCT DESCRIPTION: freeze-dried vaccine is a preparation of modified live virus (MLV) strains of IBR, BVD Types 1 and 2, PI3 and BRSV. The liquid fraction 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*.

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 subcutaneously or intramuscularly. In accordance with Beef Quality Assurance guidelines, this product should be administered SC in the neck region.

Primary Vaccination: Administer a single 2-mL dose to all breeding cows approximately 1 month prior to breeding or being added to the herd, followed by a single dose of Spirovac® L5 4-6 weeks later. 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 at least 30 days prebreeding.

Revaccination: Historically, annual revaccination with this product was recommended. The need for annual 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 is recommended.

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.

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.

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.

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.

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 (USA).

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 4469.24

Zoetis Inc., Kalamazoo, MI 49007

5-dose vial of vaccine, rehydrate to 20 mL 10-mL vial of sterile diluent	50029901
10-dose vial of vaccine, rehydrate to 20 mL 20-mL vial of sterile diluent	
50-dose vial of vaccine, rehydrate to 20 mL 100-mL vial of sterile diluent	

CPN: 3690257.7