ZOETIS INC.

333 PORTAGE STREET, KALAMAZOO, MI, 49007

Telephone: 269-359-4414 Customer Service: 888-963-8471 Website: www.zoetis.com



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STAYBRED® VL5

Zoetis

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

This product has been shown to be effective for the vaccination of healthy cows and heifers against disease caused by *Campylobacter fetus*, *Leptospira canicola*, *L. grippotyphosa*, *L. hardjo*, *L. icterohaemorrhagiae*, *and L. pomona*. Duration of immunity has not been established. For more information regarding efficacy and safety data, go to productdata.aphis.usda.gov.

SAFETY AND EFFICACY: Because the fractions of StayBred VL5 are inactivated, they cannot replicate in vaccinated animals. Vaccine fractions stimulated satisfactory geometric mean antibody titers for protection. In safety studies of the StayBred VL5 fractions, no adverse reactions to vaccination were reported.

Efficacy of each fraction of StayBred VL5 was demonstrated in challenge-of immunity tests. Cattle vaccinated with any fraction of StayBred VL5, followed by challenge with a disease-causing strain of that fraction, showed no clinical signs or had fewer signs than nonvaccinated control cattle. Serologic studies also demonstrated no immunologic interference among the fractions of StayBred VL5.

DIRECTIONS:

General Directions: Shake well. Aseptically 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 two 2-mL doses 2-4 weeks apart to all breeding-age cows and heifers 30-60 days before exposure or being added to the breeding herd.

Revaccination: Historically, annual revaccination with this product has been 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 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.

Do not vaccinate within 21 days before slaughter.

This product has not been tested in pregnant animals.

Contains thimerosal as a preservative.

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. 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.

In case of human exposure, contact a physician.

Technical inquiries should be directed to Zoetis Inc. Technical 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 2863.02 40038511 Zoetis Inc., Kalamazoo, MI 49007, USA

Presentation: 50 dose vial.

CPN: 3690070.4