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One Shot Ultra® 8

Zoetis

Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D-Mannheimia Haemolytica Bacterin-Toxoid

This product has been shown to be effective for the vaccination of healthy cattle against disease caused by *Clostridium chauvoei, Cl. septicum, Cl. haemolyticum, Cl. novyi, Cl. sordellii, Cl. perfringens* types C and D, and respiratory disease caused by *Mannheimia haemolytica* type A1. Duration of immunity has not been established. For more information regarding efficacy and safety data, see productdata.aphis.usda.gov.

Although *Cl. perfringens* type B is not a significant problem in North America, immunity is provided by the beta toxoid of type C and the epsilon toxoid of type D.

The freeze-dried component is a preparation of inactivated whole cultures of *M. haemolytica* propagated to increase the production of leukotoxin and capsular and cell-associated antigens. The liquid component consists of killed, standardized cultures of *Cl. chauvoei, Cl. septicum, Cl. haemolyticum, Cl. novyi, Cl. sordellii*, and *Cl. perfringens* types C and D, with a special, water-soluble adjuvant (Stimugen™) to enhance the immune response.

DISEASE DESCRIPTION: Pneumonia caused by *M. haemolytica* type A1 has resulted in substantial economic losses in the cattle industry. The disease condition, known as shipping fever, often prevents optimal weight gain in infected cattle and may result in death. Clinical signs may include difficult breathing, nasal discharge, reduced feed intake, fever, and increased pulse rate.

M. haemolytica type A1, a normal constituent of the bovine nasopharynx, increases greatly in number when an animal undergoes stress (transport, change in climate, viral infections). This rapid increase in bacterial population adds to the deposition of organisms in the lungs. In the lung, *M. haemolytica* type A1 may grow rapidly and produce a leukotoxin which incapacitates leukocytes (alveolar macrophages and polymorphonuclear neutrophils). When the bacterium is engulfed by a weakened leukocyte, the leukocyte is unable to destroy the bacterium, allowing the bacterium to produce leukotoxin, which kills the leukocyte. As the leukocyte dies, it releases enzymes that add to the fibrinopurulent consolidation and local areas of necrosis characteristic of pneumonia caused by *Mannheimia haemolytica* type A1 (shipping fever).

SAFETY AND EFFICACY: In safety studies involving 595 animals, no untoward reactions were noted following vaccination. Vaccination did result in small, temporary injection site swellings.

Efficacy of One Shot Ultra 8 against *M. haemolytica* was demonstrated in a challenge-of-immunity study. Cattle (300-550 lb) vaccinated with 1 dose of One Shot Ultra 8 were subjected to severe experimental challenge at 2 weeks postvaccination with a heterologous strain of *M. haemolytica* type A1. Four days postchallenge, animals were necropsied and individual lungs were evaluated for lung damage and lesions characteristic of *M. haemolytica* type A1 infection. Vaccinates demonstrated a statistically significant reduction (82.6%) in lung damage compared to animals receiving a placebo. Immunogenicity of the clostridial fractions was confirmed by serologic studies.

DIRECTIONS:

General Directions: Mix accompanying vial of diluent well. Aseptically rehydrate the freeze-dried bacterin-toxoid, mix well, and administer 2 mL subcutaneously. In accordance with Beef Quality Assurance guidelines, this product should be administered SC under the skin.

Primary Vaccination: Administer a single 2-mL dose to healthy cattle, followed by a second 2-mL dose of UltraChoice® 8, 4-6 weeks later.

Revaccination: Historically, annual revaccination with a single dose of UltraChoice 8 has been recommended. For more information on revaccination and in the face of exposure, contact your veterinarian.

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

PRECAUTIONS:

Store at 2°-8°C. Prolonged exposure to higher temperatures 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 vaccinate within 21 days before slaughter.

Not for use in sheep.

Contains formalin as a preservative.

Temporary local swelling at injection site may occur after administration.

Field reports and a clinical study indicate that a transient reduction in milk production may occur following vaccination of lactating dairy cattle.

This product has not been tested in pregnant animals.

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 on the label.

In case of human exposure, contact a physician.

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.

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

For veterinary use only

VLN 190/PCN 7460.00

Zoetis Inc., Kalamazoo, MI 49007, USA

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Presentation: 10 doses and 50 doses.

CPN: 3690074.4