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

One Shot Ultra® 8

PRODUCT DESCRIPTION: One Shot Ultra 8 is for vaccination of healthy cattle as an aid in preventing blackleg caused by Clostridium chauvoei, malignant edema caused by Cl. septipectum; facultaiy hemoglobinuria caused by Cl. haemolyticum; black disease caused by Cl. novyi; gas gangrene caused by Cl. septicum; enterotoxemia and enteritis caused by Cl. perfringens types B, C, and D; and bronchopneumonia caused by Mannheimia haemolytica type A1. Although Cl. perfringens type B is not a significant problem in North America, immunity is provided by the beta toxin of type C and the epsilon toxin 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. septipectum, Cl. haemolyticum, Cl. novyi, Cl. septicum, and Cl. perfringens types C and D, with a special, water-soluble adjacent illitrogen® 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 depositions of organisms in the lungs. In the lung, M. haemolytica type A1 may grow rapidly and produce a leukotoxin which incapacitates leukocytes (neutrophils and monocytes). When the bacterium is engulfed by a weakened leukocyte, the leukocyte is unable to destroy the bacteria, allowing the bacteria 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. (Shedding level).

SAFETY AND EFFICACY: In safety studies involving 595 animals, no untoward reactions were noted following vaccination. Vaccination did result in small, temporary-site swellings. Efficacy of One Shot Ultra 8 against M. haemolytica was demonstrated in a challenge-immunity study. Cattle (360–550 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. Vaccines demonstrated a statistically significant reduction (82.5%) in lung damage compared to animals receiving a placebo. Immune reactivity of the clinical challenge was confirmed by serologic studies.

DIRECTIONS: 1. General Directions: Vaccination of healthy cattle is recommended. Aspecifically rehydrate the freeze-dried bacteria-toxoid (One Shot Ultra 8) by shaking well, and administer 2 mL subcutaneously. In accordance with Beef Quality Assurance guidelines, this product should be administered subcutaneously (SC) under the skin.

2. 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. For Cl. haemolyticum repeat the dose every 8 months in animals subject to exposure.

3. Revaccination: Annual revaccination with a single dose of UltraChoice 8 is recommended. Good management practices support revaccination with One Shot® whenever subsequent stress or exposure is likely.

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

PRECAUTIONS:
1. Store at 2°–7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
2. Use entire contents when first opened.
3. Sterilized syringes and needles should be used to administer this vaccine.
4. Do not vaccinate within 21 days before slaughter.
5. Not for use in sheep.
6. Contains formalin as a preservative.
7. Temporary local swelling at injection site may occur after administration.
8. Field reports and a clinical study indicate that a transient reduction in milk production may occur following vaccination of lactating dairy cattle.
9. As with many vaccines, anaphylaxis may occur after use. Initial administration of epinephrine is recommended and should be followed with appropriate supportive therapy.

This product has been shown to be efficacious in healthy animals. A protective immune response may not be elicited if animals are inoculating 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.

REFERENCES:
3. Technical inquiries should be directed to Zoetis Inc. Veterinary Services, (888) 963-8471 (USA), (800) 461-0917 (Canada).

For veterinary use only.

Zoetis Inc.
Kalamazoo, MI 49007, USA

(888) 963-8471 (USA), (800) 461-0917 (Canada).

T35 Pan 1:3 05/11/2003 US

Date: 03/15/17 1:07 PM

Page dimensions: 792.0x1245.0