

# Bovine Rhinotracheitis- Virus Diarrhea- Parainfluenza<sub>3</sub>- Respiratory Syncytial Virus Vaccine Modified Live Virus



## Haemophilus Somnus Bacterin

### Resvac® 4/Somubac®

**PRODUCT DESCRIPTION:** Resvac 4/Somubac is for vaccination of healthy, nonpregnant cattle as an aid in preventing infectious bovine rhinotracheitis caused by infectious bovine rhinotracheitis (IBR) virus, bovine viral diarrhea caused by bovine viral diarrhea (BVD) Type 1 virus, and disease caused by parainfluenza<sub>3</sub> (PI<sub>3</sub>) virus, bovine respiratory syncytial virus (BRSV), and *Haemophilus somnus*. Resvac 4/Somubac consists of a standardized combination of freeze-dried, attenuated strains of IBR, BVD Type 1, PI<sub>3</sub>, and BRSV viruses propagated in stable cell lines; accompanied by liquid, inactivated, standardized *Haemophilus somnus* bacterin diluent. Somubac is prepared from selected strains of *Haemophilus somnus* which are grown serum-free in an environmentally controlled fermentation system and inactivated in such a manner as to maintain their immunogenic integrity. The bacterin is adjuvanted with aluminum hydroxide. The vaccine viruses are produced under the precisely controlled conditions of Zoetis Inc.'s Frozen Stable Cell Bank™ system. The use of this special cell system in producing Resvac 4 ensures freedom from potentially harmful adventitious agents. The vaccine viruses are blended with a special stabilizer and presented in freeze-dried form. The product is tested for purity, safety, potency, and efficacy in accordance with the regulations of the United States Department of Agriculture. Experimental studies have shown that transmission of the vaccinal BVD virus from 27 vaccinated cattle to 9 susceptible contact controls (including 4 pregnant cows) did not occur.

**DISEASE DESCRIPTION:** IBR, commonly known as "red nose" disease, is a mild to very acute inflammation of the upper respiratory tract in cattle. Infection with IBR virus may result in the following syndromes: a respiratory form, abortion, encephalitis, conjunctivitis, enteritis, and genital infections.

BVD infection can cause a variety of clinical signs in cattle, including fever, mild to severe leukopenia, lacrimation, corneal opacity, various respiratory related signs, mucosal disease, diarrhea, and abortion. Sub-clinical infection is common and may predispose animals to subsequent respiratory or enteric disease.

Parainfluenza is an upper respiratory infection in cattle characterized by fever, mild leukopenia, serous nasal discharge, coughing, and lacrimation. The causative virus, PI<sub>3</sub>, is often isolated and recognized as a pre-disposing infection in shipping fever and as a complicating entity in outbreaks of pasteurellosis, IBR, BVD, and BRSV disease. The infection may be mild or inapparent or frequently may be concurrent with other bacterial and viral agents.

Laboratory diagnosis of BRSV has proven difficult, and only recently has it gained recognition as an important component of the bovine respiratory disease complex. As a causative agent, the virus is a pathogen of the lower respiratory tract with characteristic clinical signs of serous nasal discharge, coughing, lacrimation, and pyrexia. Subclinical infections can occur and have been shown to predispose cattle to secondary bacterial infections. Based on antibody prevalence, approximately 2/3 of all herds, both beef and dairy, have been exposed. Exacerbation of clinical signs has been documented when concurrent BRSV and BVD or IBR infection exists.

Diseases associated with *Haemophilus somnus* are widespread and occur sporadically in beef and dairy cattle populations. Several disease manifestations are observed. In the respiratory form, the infected animal develops an acute fibrinous pneumonia and pleuritis. The disease may become septicemic, with the involvement of most tissues and organs. A temperature response from 106°–108°F is common. If death does not occur, the animal becomes a poor weight gainer, and may develop other signs such as arthritis, knuckling, and a dry, hacking cough. Another disease manifestation resulting from septicemia is infectious

thromboembolic meningoencephalitis (TEME), which can occur without any obvious respiratory involvement. The septicemia may lead to vasculitis and thrombosis, and disease can be expressed in several syndromes. Many times the first sign of the disease is finding dead cattle. Early signs are stiffness, listlessness, and high temperatures.

Circling may occur with abnormal eye movements, along with muscular tremors due to CNS involvement. Death occurs in a few hours in acute cases.

*Haemophilus somnus* has also been incriminated in reproductive disorders of beef and dairy cattle.

**Purity**—The master seed viruses were purified using the latest available procedures to assure the highest degree of purity. The master cell stocks were prepared and pretested for use in vaccine production. The master cell stocks and master seed viruses were found to be negative for bacteria, fungi, mycoplasma, and adventitious viruses.

**SAFETY AND EFFICACY:** Studies in cattle show Resvac 4/Somubac to be safe and free from untoward reactions. This product was field tested in thousands of cattle by practicing veterinarians. No undesirable effects attributable to the product were noted. Vaccination/challenge studies in cattle showed each fraction contained in Resvac 4 to be effective as an aid in the prevention of disease caused by IBR, BVD Type 1, PI<sub>3</sub> and BRSV viruses. Cattle vaccinated with Somubac were protected against challenge with a highly virulent strain of *Haemophilus somnus*. Antigen interference studies in cattle show each fraction of the Resvac 4/Somubac combination to be compatible.

#### DIRECTIONS:

- General Directions:** Vaccination of healthy, nonpregnant cattle is recommended. Aseptically rehydrate the freeze-dried vaccine with the liquid bacterin provided, shake 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:** Healthy, nonpregnant cattle 3 months of age or older should receive 2 doses administered 2–4 weeks apart.
- Revaccination:** Annual revaccination with a single dose is recommended. Calves with maternal antibodies may not develop or maintain satisfactory levels of immunity; therefore, calves vaccinated before 6 months of age should be revaccinated at 6 months of age or at weaning.
- Good animal husbandry and herd health management practices should be employed.

#### PRECAUTIONS:

- Do not use in pregnant cows (abortions can result) or in calves nursing pregnant cows.
- Store at 2°–7°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.
- Burn containers and all unused contents.
- Do not vaccinate within 21 days before slaughter.
- Contains polymyxin B and neomycin 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.
- 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. Technical Services, (888) 963-8471 (USA), (800) 461-0917 (Canada).

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