Bovine Rhinotracheitis-Parainfluenza$_3$ Vaccine

Modified Live Virus

For intranasal use

TSV-2®

PRODUCT DESCRIPTION: TSV-2 is for vaccination of healthy cattle, including pregnant cows, as an aid in preventing infectious bovine rhinotracheitis caused by infectious bovine rhinotracheitis (IBR) virus and disease caused by parainfluenza$_3$ (PI$_3$) virus. The vaccine is prepared by growing attenuated virus strains on a bovine cell line. The virus fractions are combined and stabilized by freeze-drying. A sterile diluent is supplied for rehydration.

TSV-2 is unique in that the virus strains it contains are temperature-specific. Tests have shown that they will not grow *in vivo* at or above 39°C,[1] the normal bovine body temperature. This restricts viral replication to the nasal mucosa, which is constantly ventilated and maintained at temperatures less than 39°C, even in the febrile animal. At this localized site, the temperature-specific viruses replicate and stimulate local and systemic immunity.[2] Because the temperature-specific strains cannot grow in the internal body organs or developing fetus, pregnant cows may be safely vaccinated. Stimulation of a localized immune response also results in a rapid onset of protection.[3,4]

DISEASE DESCRIPTION: IBR is a prevalent viral respiratory disease characterized by fever, nasal discharge, conjunctivitis, a hyperemic muzzle ("red nose"), coughing, and increased respiration. In pregnant cows, IBR virus can also cause abortions.

PI$_3$ is a common viral respiratory infection, sometimes mild or inapparent, but often associated with bovine respiratory disease complex.

SAFETY AND EFFICACY: Safety of the temperature-specific IBR strain was demonstrated in a test where it was administered to 1,019 pregnant cows in 12 herds.[5] No abortions attributed to IBR were observed. In a controlled challenge-of-immunity test, 5 of 5 susceptible vaccinates were protected from a virulent IBR challenge that clinically affected all 5 nonvaccinated control calves. In a second challenge-of-immunity test, all 25 vaccinated calves were protected from a virulent PI$_3$ challenge that produced clinical signs or temperature increase in 6 of 7 nonvaccinated control calves. In an onset-of-protection study, 2 pairs of susceptible calves remained clinically normal when subjected to contact challenge 72 and 48 hours after vaccination with virulent IBR virus. One calf challenged 24 hours postvaccination remained normal, another exhibited mild clinical signs. All control calves and calves used for contact challenge were clinically affected.[4]

DIRECTIONS:

1. *General Directions:* Vaccination of healthy cattle, including pregnant cows, is recommended. Aseptically rehydrate the freeze-dried vaccine with the sterile diluent provided, shake well, and administer 2 mL intranasally using a cannula or a syringe with the needle removed. Place half the dose (1 mL) in each nostril.
2. *Primary Vaccination:* Administer a single 2-mL dose to healthy cattle. Calves vaccinated before the age of 6 months should be revaccinated after 6 months of age to avoid possible maternal antibody interference with immunization.
3. *Revaccination:* Annual revaccination with a single dose is recommended.
4. Good animal husbandry and herd health management practices should be employed.

PRECAUTIONS:

1. Store at 2°–7°C. Prolonged exposure to higher temperatures and/or direct sunlight 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. Do not sterilize with chemicals because traces of disinfectant may inactivate the vaccine.
4. Burn containers and all unused contents.
5. Do not vaccinate within 21 days before slaughter.
6. Contains gentamicin as preservative.
7. As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.
8. 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.
9. 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.

REFERENCES:

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2. Zygraich N, Lobmann M, Peetermans J, *et al:* Local and systemic response after simultaneous intranasal inoculation of temperature-sensitive mutants of parainfluenza$_3$, IBR and bovine adenovirus$_3$. *Devel Bio Stan* 28:482–488, 1975.
3. Todd JD, Volenec EJ, Paton IM: Intranasal vaccination against infectious bovine rhinotracheitis: Studies on early onset of protection and use of the vaccine in pregnant cows. *JAVMA* 159:1370–1374, 1971.
4. Kucera CJ, Beckenhauer WH: Time required to stimulate protection with intranasal administration of a temperature-sensitive, infectious bovine rhinotracheitis virus vaccine. *Vet Med* 73:83–87, 1978.
5. Kucera CJ, White RG, Beckenhauer WH: Evaluation of the safety and efficacy of an intranasal vaccine containing a temperature-sensitive strain of infectious bovine rhinotracheitis virus. *Am J Vet Res* 39:607–610, 1978.

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