

ELANCO ANIMAL HEALTH

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TITANIUM® 5

Elanco

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine

Modified Live Virus

from the *Signature cell line*®

IBR-BVD-PI₃-BRSV

CONTENTS:

Infectious Bovine Rhinotracheitis Virus (IBR), Modified Live Virus

Bovine Virus Diarrhea Virus (BVD), Modified Live Virus

Bovine Parainfluenza₃ Virus (PI₃), Modified Live Virus

Bovine Respiratory Syncytial Virus Vaccine (BRSV), Modified Live Virus

PRODUCT DESCRIPTION:

Titanium® 5 contains desiccated Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza₃-Respiratory Syncytial Virus Vaccine and sterile diluent to use as a diluent. Titanium® 5 is a multiantigenic modified live vaccine to be used as an aid in the prevention of disease caused by infectious bovine rhinotracheitis virus (IBR), bovine virus diarrhea virus (BVD), bovine parainfluenza₃ virus (PI₃), and bovine respiratory syncytial virus (BRSV). The five viral antigens are combined in the proper ratio, stabilized and desiccated.

The desiccated fraction contains no bovine serum, virtually eliminating extraneous virus contamination and possible allergic reactions. Controlled tests conducted in our laboratory demonstrated that animals receiving a 10x dose did not shed BRSV or PI₃ viruses. Control animals, housed with vaccinates, remained seronegative throughout the testing period.

DISEASES:

Serologic surveys indicate the five viruses are widespread in the cattle population. The viruses are considered contributors to the respiratory disease complex of cattle. Multiple infections do occur, and secondary bacterial infections may exacerbate the disease signs.

Infectious Bovine Rhinotracheitis Virus

IBR is an acute upper respiratory disease. Signs of IBR may include elevated temperature, hyperpnea, dyspnea, excessive nasal and ocular discharge, rapid breathing, cough and depression. Reproductive problems including abortions have been observed.

Bovine Virus Diarrhea Virus

BVD is often obscured or confused with other conditions of the respiratory disease complex. Clinical signs may include fever, anorexia, coughing, depression, diarrhea, and occasional lameness. BVD may be inapparent, chronic, or a fatal mucosal disease. BVD may cause suppression of the immune system. Affected animals have increased susceptibility to secondary infections. BVD in pregnant animals may cause abortions or malformed and weak calves at birth. Chronic disease with erosions in the alimentary tract is referred to as "Mucosal Disease" and is usually fatal.

Bovine Parainfluenza₃ Virus

Parainfluenza₃ infections may cause few noticeable signs. Disease signs caused by PI₃ virus generally appear within 14 days after shipment and arrival of calves at their destination. Signs are weakness, depression, watery to mucopurulent nasal discharge, fever, coughing, and weight loss. PI₃ is a contributor to the Bovine Respiratory Disease Complex. Antibodies are present in over 80% of young calves.

Bovine Respiratory Syncytial Virus

BRSV infections occur in dairy and beef cattle of all ages, including nursing calves. BRSV signs follow an incubation of 5 to 7 days. Infected calves and adult animals exhibit signs of acute respiratory disease that may include fever,

cough, rapid breathing, subcutaneous edema of the throat and neck, depression, nasal discharge, ocular discharge, anorexia, hyperpnea, pulmonary edema and emphysema. BRSV may predispose cattle to secondary infections, particularly bacterial pneumonia. In an acute outbreak, sudden death has been reported. Enzootic pneumonia of dairy calves associated with BRSV may occur at 10 days of age. BRSV signs vary in severity but may rapidly progress to a crisis phase. Recovery of adult animals is rapid and usually uneventful.

Diagnosis is difficult both in the field and laboratory. After the animal exhibits signs of disease, the virus usually is not isolated. Paired serum samples may assist in determining existing herd infections. Surveys indicate BRSV antibodies are present in over 90% of calves in North America.

EFFICACY:

Efficacy was demonstrated by vaccination and challenge studies. Following vaccination, seroconversion occurred in 81% of the calves receiving a single vaccination, and 100% after 2nd vaccination. Following challenge, vaccinated animals exhibited significant reduction of morbidity and clinical signs. In contrast, unvaccinated challenged calves exhibited clinical signs of extended duration, increased severity and extended virus shedding.

IMMUNE RESPONSES:

Research demonstrated Titanium® 5 is safe and efficacious however; individual animals may be unable to develop an adequate immune response following vaccination due to: concurrent disease, malnutrition, parasitism, or stress due to shipment or environmental conditions.

SAFETY:

Safety in pregnant heifers and cows was demonstrated in trials conducted at three separate sites. The heifers and cows were vaccinated prior to breeding with Titanium® 5 L5 HB, followed by a post-breeding vaccination at the first, second or third trimester of pregnancy. The cows were observed from pregnancy vaccination through calving for fetal loss. Heifers and cows vaccinated with Titanium® 5 L5 HB had abortions and calving rates similar to the control cows. Calving Rates (normal calves delivered/total deliveries)

Trimester	Controls	Vaccinates
1	205/213 (96.24%)	201/209 (96.17%)
2	295/310 (95.16%)	305/315 (96.83%)
3	197/208 (94.71%)	198/205 (96.59%)
Total	697/731 (95.35%)	704/729 (96.57%)

The fetal loss in the two groups was similar with 3.43% in the Titanium® 5 L5 HB vaccinated groups and 4.65% in the control groups. Following calving, each calf's health was monitored for 4 weeks. The health of the calves in the Titanium® 5 L5 HB vaccinated dams was similar to the health of calves born to the control dams. **WARNING:** Fetal health risks associated with vaccination of pregnant animals with modified live vaccines cannot be unequivocally determined by clinical trials conducted for licensure. Vaccination of pregnant animals with modified live vaccines should be discussed with a veterinarian.

INDICATIONS FOR USE:

Titanium® 5 contains BVD Type I and BVD Type II and is recommended for the vaccination of healthy cows and heifers, no less than 30 days prior to breeding, as an aid in the prevention of disease caused by infectious bovine rhinotracheitis virus (IBR), bovine virus diarrhea virus, Type I (BVD), bovine virus diarrhea virus, Type II (BVD), bovine parainfluenza₃ virus (PI₃), and bovine respiratory syncytial virus (BRSV). **Titanium® 5 may be administered to pregnant cattle provided they were vaccinated, according to label directions, with Titanium® 3, Titanium® 4 L5, Titanium® 5 or Titanium® 5 L5 HB 30 to 60 days prior to breeding. Titanium® 5 may also be administered to calves nursing pregnant cows provided their dams were vaccinated as described above.**

DOSAGE AND ADMINISTRATION:

Rehydrate the desiccated vial with accompanying diluent and shake well. Inject 2 mL subcutaneously using aseptic technique, followed by a second dose of monovalent bovine respiratory syncytial virus vaccine (Titanium® BRSV) to be given 14 to 28 days after the first dose. Annual revaccination is recommended. Calves vaccinated before weaning should be revaccinated 30 days after weaning when the possible influence of maternal antibodies is decreased.

CAUTIONS:

Recommended for the vaccination of healthy cows and heifers no less than 30 days prior to breeding. Titanium® 3, Titanium® 4 L5, Titanium® 5 or Titanium® 5 L5 HB can also be administered to pregnant cattle provided they were vaccinated, according to label directions, with Titanium® 3, Titanium® 4 L5, Titanium® 5 or Titanium® 5 L5 HB 30 to 60 days prior to breeding. Failure to follow label directions may result in abortions. The Titanium line may be administered to calves nursing pregnant cows provided their dams were vaccinated as described above. Store at 35° to 46° F (2° to 8° C). DO NOT FREEZE. Use entire contents when first opened. Allergic reactions may follow the use of vaccines; **ANTIDOTE: Epinephrine. Do not vaccinate within 21 days before slaughter. Burn container and all unused contents.**

FOR USE IN ANIMALS ONLY

SUPPLIED:

Code:	0893	10 dose (20 mL)	50 per case
	0994	50 dose (100 mL)	20 per case

Manufactured by: Diamond Animal Health, Inc., Des Moines, Iowa 50327 U.S.A.

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