INFORCE 3®

Zoetis

Bovine Rhinotracheitis-Parainfluenza$_3$-Respiratory Syncytial Virus Vaccine

Modified Live Virus

For intranasal use only

INDICATIONS: For vaccination of healthy cattle 3 days of age or older, including pregnant cows, to prevent respiratory disease caused by bovine respiratory syncytial virus (BRSV), and as an aid in preventing respiratory disease caused by infectious bovine rhinotracheitis (IBR) virus and parainfluenza$_3$ (PI$_3$) virus. A duration of immunity of at least 193 days has been demonstrated against IBR; duration of immunity against BRSV and PI$_3$ has not been established.

DESCRIPTION: INFORCE 3 is a freeze-dried preparation of temperature-sensitive strains of IBR and PI$_3$ viruses and modified live BRSV, packaged with a sterile diluent for rehydration.

SAFETY AND EFFICACY:

In a safety study conducted with INFORCE 3, no significant adverse reactions related to vaccination were observed. Safety has been demonstrated in calves as young as 0 days of age, weaned calves, high-stressed stockers, and pregnant cows in all 3 trimesters.

Efficacy of the BRSV fraction of INFORCE 3 was demonstrated in two vaccination-challenge studies. Calves were administered either a single 2-mL dose in one nostril or 1-mL doses in each nostril. One hundred percent of calves as young as 3 days of age, vaccinated with a 2-mL dose administered in a single nostril and challenged 49 and 57 days later survived virulent challenge. In both studies, INFORCE 3 vaccinates experienced significantly lower mortality, significantly less lung damage and significantly less viral shedding for a significantly shorter duration than control cattle.

Efficacy of the PI$_3$ fraction was also demonstrated in two vaccination-challenge studies, conducted as described above. In both studies, calves vaccinated with INFORCE 3 were protected against a virulent PI$_3$ challenge, as evidenced by shortened durations of virus shedding, when compared with non-vaccinated control calves.

Short- and long-term efficacy of the IBR fraction were demonstrated in two studies. In the first study, weaned, 7- to 9-month-old vaccinated calves demonstrated 95% less incidence and a 95.6% reduction in disease duration compared to controls when challenged 28 days after vaccination.

Researchers also saw favorable impacts on rectal temperatures and nasal shedding of virus. In the second study, calves as young as 3 days of age were vaccinated with a single 2-mL dose and challenged more than 6 months (193 days) later. Vaccinates were observed to have 75.6% less incidence of IBR and a 63.8% reduction in duration of disease compared to controls. Favorable impacts on temperature, nasal shedding, and antibody titers were also seen.

DIRECTIONS:

General Directions: Aseptically rehydrate the freeze-dried vaccine with the sterile diluent provided, shake well, and administer 2 mL intranasally (IN) using a cannula or a syringe with the needle removed.

Primary Vaccination: Place the 2-mL dose in one nostril, or half the dose (1 mL) in each nostril. The presence of maternal antibody is known to interfere with the development of active immunity in cattle, and additional boosters will be required in most young animals.

For advice on revaccination frequency, consult your veterinarian or the manufacturer.

PRECAUTIONS:

Store at 2°-8°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 should be used to administer this vaccine. Do not sterilize with chemicals because traces of disinfectant may inactivate the vaccine.

Inactivate unused contents before disposal.

Do not vaccinate within 21 days before slaughter.

Contains gentamicin as preservative.

Fetal health risks associated with the vaccination of pregnant animals with modified live vaccines cannot be unequivocally determined during clinical trials conducted for licensure. Appropriate strategies to

address the risks associated with modified live vaccine use in pregnant animals should be discussed with a veterinarian.

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 above.

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 1071.23

Zoetis Inc., Kalamazoo, MI 49007, USA

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1-dose vial of vaccine, rehydrate to 2 mL 2-mL vial of sterile diluent	
10-dose vial of vaccine, rehydrate to 20 mL 20-mL vial of sterile diluent	
25-dose vial of vaccine, rehydrate to 50 mL 50-mL vial of sterile diluent	
50-dose vial of vaccine, rehydrate to 100 mL 100-mL vial of sterile diluent	5266000 11248800

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