BOEHRINGER INGELHEIM VETMEDICA, INC.

2621 NORTH BELT HIGHWAY, ST. JOSEPH, MO, 64506-2002

Telephone: 800-325-9167
Fax: 816-236-2717
Website: www.bi-vetmedica.com
www.productionvalues.us
www.thinkmetacam.com
www.vetmedin-us.com
www.yourdogsheart.com
Email: info@productionvalues.us

EXPRESS® FP 10

Boehringer Ingelheim

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin

Indications

For vaccination of healthy, susceptible cows and replacement heifers prior to breeding to prevent persistently infected calves caused by Bovine Virus Diarrhea Types 1 and 2. Four non-cytopathic BVD challenge viruses were used in five different challenge studies to determine the efficacy of this product in preventing persistently infected calves due to BVD Types 1 and 2. The challenge viruses included two BVD Type 1b and two BVD Type 2 strains.

For vaccination of healthy, susceptible cattle as an aid in the reduction of respiratory diseases caused by Bovine Rhinotracheitis (IBR) virus, Bovine Virus Diarrhea (BVD) Types 1 and 2, Parainfluenza 3 (PI3) virus, Bovine Respiratory Syncytial Virus (BRSV), and leptospirosis caused by *Leptospira canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae,* and *L. pomona.* This vaccine may be used in pregnant females or calves nursing pregnant females, provided the females were vaccinated pre-breeding according to label directions with any Express® FP vaccine. See below for details.

Composition

The product in the amber glass vial contains IBR, BVD Type 1 (Singer 1a cytopathic) and Type 2 (296 cytopathic), PI3, and BRSV modified live viruses. The plastic vial contains the *Leptospira* organisms listed above, in a unique adjuvant system. Contains neomycin and Amphotericin B as preservatives.

Directions and Dosage

Shake the accompanying bottle of bacterin diluent, then rehydrate the modified live virus vaccine by aseptically adding the diluent to the vaccine vial. Shake the rehydrated vaccine and use immediately. Using aseptic technique, inject 2 mL subcutaneously in front of the shoulder and midway of the neck,

away from the suprascapular lymph node. If initial vaccination, repeat with BRSV and *Leptospira* vaccines in 14-28 days. Calves vaccinated before 6 months of age should be revaccinated at 6 months or at weaning. A 2 mL booster dose is recommended annually. Cows and Heifers: Using aseptic technique, annually inject a single 2 mL dose subcutaneously at or about 4 weeks prior to breeding. Pregnant cows and nursing calves may be vaccinated following the pre-breeding vaccination. See below for details. If initial vaccination, see above.

Precautions

Store out of direct sunlight at 35-45°F (2-7°C). Avoid freezing. Use entire contents when first opened. Do not vaccinate within 21 days before slaughter. Stressed cattle should not be vaccinated. Burn vaccine container and all unused contents. Injection site swelling may occur. Anaphylactoid reactions may occur. Antidote: Epinephrine.

Summary of Pregnant Cow Safety Study

Safety in pregnant cows and heifers was demonstrated in a field study that utilized more than 1600 cattle from three separate herds, as well as a serological study from a fourth herd. All cows and heifers enrolled in the study were vaccinated prior to breeding with Express® FP 10, a modified live virus (MLV) vaccine containing Infectious Bovine Rhinotracheitis (IBR), Bovine Virus Diarrhea (BVD) Type 1, BVD Type 2, Parainfluenza 3 (PI3), and Bovine Respiratory Syncytial Virus (BRSV), as well as *Leptospira canicola, L. grippotyphosa, L. hardjo, L. icterohaemorrhagiae, L. pomona* bacterin. Approximately one-third of the enrolled cattle were assigned to each one of the three trimesters. After confirmation of pregnancy status, a second vaccination was administered during the assigned trimester. Half of each trimester group was given Express® FP 10 and the remaining half was given the Lepto 5 bacterin. All of the enrolled cattle were observed closely through calving. Any fetal losses were recorded and fetuses were subjected to a full necropsy. Fetal losses were similar in both treatment groups. Overall fetal losses were 1.6% (13 of 810) in the test vaccination group and 1.9% (15 of 776) in the control group. There were no abortions or fetal losses diagnosed as due to IBR or BVD. The health of the calves from the enrolled cattle was monitored for 30 days after birth. There were no differences noted in the health status of calves between the two treatment groups.

In addition, a separate newborn calf serology study was conducted. A total of 120 calves from dams revaccinated in the second or third trimester were negative for pre-colostral antibodies to Bovine Virus Diarrhea Types 1 and 2 and Infectious Bovine Rhinotracheitis, further demonstrating that the Express® MLV products do not cause fetal infection when administered during pregnancy to previously vaccinated cows or heifers.

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.

No vaccine can be expected to have 100% efficacy under all conditions. A small number of calves persistently infected with BVDV may have a devastating effect on herd health.

Note

It is possible that healthy-appearing cattle can be persistently infected with or incubating virulent BVD virus at the time of vaccination. In view of these findings and suggested causes, BVD vaccine is contraindicated in persistently infected cattle and use should be limited only to healthy, immunocompetent, unstressed cattle.

Caution

Animal inoculation only. Accidental injection into humans can cause serious local reactions. Contact a physician immediately if accidental injection occurs.

Boehringer Ingelheim Vetmedica, Inc., St. Joseph, MO 64506
U.S. Veterinary License No. 124

Formerly Breed-Back® FP 10
27910-00

Code			
127-911	5 x 5 Doses	This package contains five 5 dose vials of MLV vaccine and five 10 mL vials of bacterin diluent.	27903-02
127-931	10 doses/Rehydrate with 20 mL	This package contains one 10 dose vial of MLV vaccine and one 20 mL vial of bacterin diluent.	27901-02
127-951	50 doses/Rehydrate with 100 mL	This package contains 50 dose vial of MLV vaccine and one 100 mL vial of bacterin diluent.	27902-02

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