Feline Infectious Peritonitis Vaccine

Modified Live Virus

For use in cats only

Primucell FIP®

PRODUCT DESCRIPTION: Primucell FIP is for intranasal (IN) vaccination of healthy cats 16 weeks of age or older as an aid in preventing feline infectious peritonitis caused by feline infectious peritonitis virus (FIPV). Primucell FIP contains an attenuated, temperature-sensitive (TS) strain of FIP virus propagated on an established feline cell line. The vaccine is freeze-dried to preserve stability.

Cats vaccinated IN with Primucell FIP develop a protective immune response and do not become hypersensitized. This practical benefit may be attributed to the temperature-sensitive Primucell FIP vaccine strain, which replicates in the upper respiratory tract, but does not spread systemically at 39°C, the cat's body temperature.

DISEASE DESCRIPTION: FIP is a complex disease of cats caused by FIPV, a coronavirus related to transmissible gastroenteritis virus (TGEV) of pigs, enteric coronavirus of dogs, and respiratory coronavirus of humans.[1]

Although scientists do not completely understand its pathogenesis, they believe that FIP is an immune-mediated disease. FIPV first multiplies in epithelial cells of the upper respiratory tract and intestine.[2] Clinically apparent FIP occurs after the virus crosses the mucosal barrier and spreads throughout the cat in infected macrophages and monocytes.

Primary FIP may be mild, consisting of fever and a slight nasal and ocular discharge. While most cats with the primary form of FIP recover, others become chronically infected carriers. Secondary FIP may develop following primary infection and appears in 2 forms: (1) Effusive or wet form, characterized by peritonitis and pleuritis with ascites and pleural effusion, and (2) Noneffusive or dry form, characterized by granulomatous inflammation of various organs and little or no exudate.[3,4] Both forms may appear together.

Once clinical symptoms occur, FIP usually takes a fatal course. The most commonly diagnosed clinical manifestation is accumulation of fluid within the peritoneal cavity with progressive, painless enlargement of the abdomen. Infected animals also may experience difficult breathing, have an elevated temperature, appear depressed, and lose weight. Other clinical symptoms, such as ocular involvement, disseminated intravascular coagulation, and renal involvement, are observed occasionally.[5] Exudate obtained from body cavities by paracentesis appears pale yellow or golden in color and is relatively clear. Hemograms of cats with FIP typically indicate a stress response. There may be a mild to moderate anemia and leukocytosis attributed to an increased percentage of neutrophils.

FIP most frequently occurs in young cats between the ages of 6 months and 2 years of age. Incidence of disease is also higher in older cats, between 11 and 15 years of age.

SAFETY AND EFFICACY: Comprehensive tests were conducted to demonstrate the safety of Primucell FIP.

In these tests, Primucell FIP did not cause illness in cats when administered intranasally. It did not cause illness in cats infected with feline leukemia, in cats exposed to feline enteric coronavirus, in dexamethasone-immunosuppressed cats, in nonvaccinated cats that survived FIP challenge, or in kittens.

Primucell FIP did not interfere with the development of an antibody response to any of the following feline vaccine antigens: feline leukemia virus, feline rhinotracheitis virus, feline calicivirus, feline panleukopenia virus, and *Chlamydia psittaci*. Conversely, none of these vaccine antigens interfered with the immunogenicity of Primucell FIP.

Efficacy of Primucell FIP also was demonstrated in a series of tests. In the first of 2 immunogenicity studies, 20 seronegative cats were vaccinated with a 2-dose primary regimen (given 3 weeks apart). All vaccinates developed FIPV antibody titers, and 17 of the 20 (85%) survived an FIPV challenge that caused FIP in 12 of 12 (100%) nonvaccinated controls. Ten of the 12 controls died. Sixteen of the 17 (94%) vaccinated cats that survived the first challenge survived a second challenge, which caused FIP in 4 of 6 nonvaccinated controls.

In the second immunogenicity study, 20 of 20 seronegative cats developed FIPV antibody titers after primary vaccination with 2 doses given 3 weeks apart. Fifteen of 20 (75%) vaccinates were protected against a challenge of immunity in which 7 of 10 (70%) nonvaccinated control cats died of FIP. All but 1 of the surviving vaccinated cats from the first challenge survived a second challenge, which killed 6 of 6 nonvaccinated controls.

In addition to protecting against homologous challenge, Primucell FIP also protected cats against a heterologous challenge strain (WSU-1146). Clinical FIP symptoms of vaccinated cats were significantly lower ($P<0.05$) than symptoms of control cats following WSU-1146 challenge. Eight of 10 (80%) vaccinated cats survived a challenge of immunity with the WSU-1146 strain of FIP in which 3 of 5 (60%) non-vaccinated controls died of FIP.

DIRECTIONS:

1. *General Directions:* Vaccination of healthy cats is recommended. Aseptically rehydrate the freeze-dried vaccine with the sterile diluent provided. Mix well. Use dropper to inoculate entire volume into nasal passages (1/2 volume into each nasal passage). Cats may sneeze or shake their heads at the time of administration.
2. *Primary Vaccination:* Healthy cats 16 weeks of age or older should receive 2 IN doses administered 3–4 weeks apart.
3. *Revaccination:* Annual revaccination with a single dose is recommended.

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. Burn containers and all unused contents.
4. Contains gentamicin as preservative.
5. Droppers should be used to administer this vaccine.
6. As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.
7. 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:

1. Lutz H, Hauser B, Horzinek MC: Feline infectious peritonitis (FIP)—the present state of

knowledge. *J Sm An Pract* 27:108–116, 1986.
2. Stoddart ME, Gaskell RM, Harbour DA, *et al:* The sites of early viral replication in feline infectious peritonitis. *Vet Microbiol* 18:259–271, 1988.
3. Holmberg CA, Gribble DH: Feline infectious peritonitis. Diagnostic gross and microscopic lesions. *Feline Pract* 3:11–14, 1973.
4. Montali RJ, Strandberg JD: Extraperitoneal lesions in feline infectious peritonitis. *Vet Path* 9:109–121, 1972.
5. Weiss RC, Dodds WJ, Scott FW: Disseminated intravascular coagulation in experimentally induced feline infectious peritonitis. *Am J Vet Res* 41(5):663–671, 1980.

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