

PFIZER INC.

PFIZER ANIMAL HEALTH

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FELOCELL® 4

Pfizer Animal Health

Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine
Modified Live Virus and Chlamydia

For use in cats only

PRODUCT DESCRIPTION: Fellocell 4 is for vaccination of healthy cats as an aid in preventing feline viral rhinotracheitis (FVR) caused by feline herpesvirus-1, feline respiratory disease caused by feline calicivirus (FCV), feline panleukopenia caused by feline parvovirus (FPV), and feline chlamydiosis caused by *Chlamydia psittaci*. Fellocell 4 contains attenuated strains of feline rhinotracheitis virus, calicivirus, and panleukopenia virus (Johnson Snow Leopard strain), and *C. psittaci*, propagated on established cell lines. Fellocell 4 is packaged in freeze-dried form with inert gas in place of vacuum.

SAFETY AND EFFICACY: Safety of Fellocell 4 was demonstrated in field trials involving 2,288 cats. The majority of cats exhibited no serious postvaccination reactions attributable to the vaccine. However, approximately 1% of vaccinated cats exhibited lethargy, anorexia, and fever after vaccination. (See PRECAUTION 7.)

Efficacy of Fellocell 4 was determined by challenge-of-immunity tests. Vaccinated cats experienced significantly less severe clinical signs than nonvaccinated control cats after challenge with virulent FVR virus, FCV, FPV, or *C. psittaci*.

Results of serological studies indicated that no immunologic interference existed among the vaccine fractions. In specific-pathogen-free cats, vaccination with Fellocell 4 stimulated serologic titers to each of the 4 vaccine fractions.

DURATION OF SEROLOGIC RESPONSE: In cats vaccinated and boosted as kittens, and then vaccinated again approximately 1 year later, revaccination with Felocell 4 has been demonstrated (under field conditions) to result in serum antibody titers that persist for 12-36 months against FPV (hemagglutination inhibition [HAI] titer $\geq 1:40$), FCV (serum neutralization [SN] titer $\geq 1:32$) and FHV (SN $\geq 1:16$).

Protection against infectious agents involves a complex interplay between humoral immunity, cellular immunity, or a combination of both. The purpose of vaccination is to induce effector cells in both these arms of the immune system. During the process, long-term immunity in the form of memory T and B lymphocytes is produced. Memory cells and antibodies interact to provide protection to an animal challenged with the same pathogen at a later date. Depending on the vaccine and the disease, antibodies may be produced that provide complete protection from disease and prevent or reduce shedding. In other cases, antibodies may play a minor or ineffective role and protection from disease relies on systemic, local cellular immunity and/or local antibody production. The role of sustained serological titers in the prevention of disease has not been confirmed.

In companion animals, immunological response to infection or vaccination has generally been evaluated by measuring the level of antibodies in serum and correlating these with protection or susceptibility. For certain diseases, such as feline panleukopenia, evaluation of antibody titers can be a valuable diagnostic indicator to determine when revaccination may be needed.^{1,2} For other diseases, a serological response has not been identified that correlates with protection. Practical knowledge of the disease, the vaccine and the patient, along with serologic test results when appropriate, is paramount in making the best recommendation for a vaccination protocol for a specific animal.

The duration and character of the immune response to the viral antigens of Felocell were determined in a multi-center serology study involving 40 small animal veterinary clinics located in the United States (38) and Canada (2). Two hundred seventy-two male and female (intact and neutered) cats of various ages, breeds, weights, lifestyles and times since last vaccination were enrolled in the study. Cats were required to be healthy, FeLV and FIV negative, ≥ 2 years old with no history of disease due to FPV, FCV or FHV, and must not have been vaccinated for 12-48 months or longer. Additionally, cats must have received at least one priming vaccination series approximately 2-7 weeks apart as a kitten and a booster vaccination approximately 8-16 months later. All previously administered vaccines were Felocell CVR or Felocell CVR-C. A blood sample was collected from each cat and serum submitted to Cornell Veterinary Diagnostic Laboratory for determination of FPV (HAI), FCV (SN) and FHV (SN) antibody titers. The samples were sent to a single diagnostic laboratory, thus ensuring a standardized test and methodology. As shown in the table below, elevated geometric mean titers were sustained for 12 to ≥ 36 months after the last booster. Since the study was conducted under field conditions with client-owned animals, it is possible that natural exposure to infectious agents could have occurred without clinical signs of infection during the course of the study. In such cases, the titers measured in the study could be the result of exposure to the disease in addition to vaccinations.

Table 1. Geometric mean titer/number of cats³

Antigen	Time Since Last Vaccination (Months)						
	12-18	19-24	25-30	31-36	37-42	43-48	>48
FPV	1036/108	732/49	1026/25	654/19	617/25	659/13	472/33
FCV	430/108	433/49	219/25	180/19	323/25	430/13	687/33
FHV	41/108	46/49	41/25	39/19	27/25	45/13	36/33

DIRECTIONS:

1. *General Directions:* Vaccination of healthy cats is recommended. Aseptically rehydrate the freeze-dried vaccine with the sterile diluent provided, shake well, and administer 1 mL intramuscularly or subcutaneously.

2. *Primary Vaccination:* Healthy cats 12 weeks of age or older should receive 2 doses administered 3-4 weeks apart. Cats vaccinated at less than 12 weeks of age should be revaccinated at 12 weeks of age.

3. *Revaccination:* Annual revaccination with a single dose is recommended, although, as recommended by the American Veterinary Medical Association and its Council on Biologic and Therapeutic Agents, the attending veterinarian should determine the frequency of revaccination based on the animal's lifestyle and risk of exposure.⁴

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. Contains gentamicin as preservative.

6. Vaccination of pregnant queens should be avoided.

7. The use of this product has been associated with fever, anorexia, and lethargy in 1% of vaccinated cats, often occurring in clusters in association with multiple concurrent vaccinations. The onset is typically delayed 7-21 days after vaccination. Symptoms may persist for 3-30 days with an average of 12 days after onset. Veterinary intervention may be required. When treatment is necessary, supportive care, steroids, and antibiotics have been utilized.

8. As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.

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.

10. In case of accidental human exposure, consult a physician.

REFERENCES:

1. Tizard I, Ni Y: Use of serologic testing to assess immune status of companion animals. *JAVMA* 213:54-60, 1998.

2. Schultz RD: Current and future canine and feline vaccination programs. *Vet Med* 93(3):233-254, 1998.

3. Study 2184Z-60-01-003, Pfizer Animal Health

4. American Veterinary Medical Association, Position Statements on Biologics, June 2001.

Technical inquiries should be directed to Pfizer Animal Health Veterinary Services, (800) 366-5288 (USA), (800) 461-0917 (Canada).

For veterinary use only

U.S. Veterinary License No. 189

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75-0209-01

25 x 1-dose vials

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