Feline Leukemia Vaccine
Killed Virus

Leukocell® 2

PRODUCT DESCRIPTION: Leukocell 2 is a multiple viral antigen vaccine for vaccination of healthy cats three weeks of age or older as an aid in preventing persistent viremia, lymphomas caused by feline leukemia viruses (FeLV), and diseases associated with FeLV infection. Leukocell 2 is prepared from FeLV-transformed lymphoid cells. Viral antigens are chemically inactivated, combined with a sterile adjuvant to enhance the immune response, and packaged in liquid form. Leukocell 2 is prepared from an FeLV-transformed lymphoid cell line that releases FeLV viral particles which are soluble in a cell culture medium. The practical benefit of this unique, patented feature is that production of immunosuppressive effects characteristic of fully assembled FeLV antigens, whether live or killed, is reduced.2–4 (See SAFETY AND EFFICACY)

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persistent cervicitis, lymphoid tumors, and FeLV-associated diseases. After basic development studies were performed to demonstrate suitability for licensing, additional data has been published attesting to the vaccine’s safety and efficacy. A lymphocytic blastogenesis assay (LBA) showed that soluble vaccine proteins produced no significant effect on LBA of cat lymphocytes when compared with control samples, an indication that the vaccine is not immunosuppressive. In a related test, cats were vaccinated with a 10-fold concentration of enhanced vaccine, and lymphocytes from these cats showed no change in blastogenesis compared with those of nonvaccinated cats. Other studies showed that Leukocell was an aid in protecting vaccinated cats from latent FeLV infections. In an immunogenicity study, 25 specific pathogen free (SPF) cats were vaccinated with a 2-dose primary regimen (2 doses were given 3 weeks apart). After the second dose, significant levels of antibodies to gp70 and FOCMA were detected as well as VN antibodies. After challenge with the Rickard strain of FeLV, which infected 100% of the control cats, more than 70% of the vaccinates were protected against establishment of persistent viremia. In contrast, 85% of unvaccinated control cats developed persistent viremia. In assessing these results, it should be noted that test cats were subjected to a far more rigorous challenge regimen than could be expected under normal exposure conditions (normal FeLV incidence after exposure is 28%15,16). All test cats (including vaccinated) were artificially immunosuppressed before challenge to enhance susceptibility to FeLV infection and tumor development. Challenge virus was administered intranasally to ensure uniform exposure that conforms to the natural route of infection, and assures optimum delivery of challenge virus. Demonstrated safety is particularly critical in the case of an FeLV vaccine. Whole FeLV virus (or killed) contains a specific envelope protein, designated gp107, that is responsible for host immunosuppression.2–4,16,17 Hyperacute safety tests of Leukocell 2 did not demonstrate any immunosuppressive effects. Kittens vaccinated with Leukocell 2 had normal postvaccination white blood cell (WBC) counts, did not become viremic, remained clinically normal, and developed gp70, FOCMA, and VN antibodies. Postvaccination reactions have been observed in about 2% of vaccinated cats. These included straining on injection, transient lassitude, depression, and brief temperature elevations. Hypersensitivity evidenced by myopathy and gastrointestinal distress (vomiting and bowel evacuation) occasionally has been reported. Although a diagnostic test for FeLV antigen is not required prior to vaccination with Leukocell 2, such a test may be beneficial in evaluating candidates for vaccination. Vaccination is of no known therapeutic value in cats with existing FeLV infection, nor will it alter the natural course of disease.

DISEASE DESCRIPTION: FeLV is associated with a complex of feline diseases. These include 2 forms of cancer: (1) lymphosarcoma, characterized by presence of tumors, and (2) leukemia, characterized by presence of malignant cells in the bloodstream. In addition, FeLV is associated with a variety of non-neoplastic diseases, including aplastic anemia, reproduction failure, sterility, Feline Retinitis Syndrome (Hypertension, Atrophy), and upper respiratory infections. The pathogenic process is extensive by the virus’s role as an immunosuppressive agent. Following chronic infection, immunosuppression eventually results in malignancies. Persistent viremia of infected cats is usually established within a few months of primary infection. FeLV malignancies do not have high FOCMA antibody titers,12 and that inad- equate anti-FOCMA response is not only of no value, but is the key to identifying cats harboring FeLV lymphosarcoma.13

SAFETY AND EFFICACY: The vaccine’s safety and lack of immunosuppres- sion have been demonstrated by the lymphocyte blastogenesis assay (LBA), differential and complete blood counts (CBC), Leukocell 2 stimulation and priming for antibody responses to gp70, p15e protein, the tumor-specific anti- gen FOCMA (see DISEASE DESCRIPTION), as well as VN antibodies. In an immunogenicity study, 25 specific pathogen free (SPF) cats were vac- cinated with a 2-dose primary regimen (2 doses were given 3 weeks apart). After the second dose, significant levels of antibodies to gp70 and FOCMA were detected as well as VN antibodies. After challenge with the Rickard strain of FeLV, which infected 100% of the control cats, more than 70% of the vaccinates were protected against establish- ment of persistent viremia. In contrast, 85% of unvaccinated control cats developed persistent viremia. In assessing these results, it should be noted that test cats were subjected to a far more rigorous challenge regimen than could be expected under normal exposure conditions (normal FeLV incidence after exposure is 28%15,16). All test cats (including vaccinated) were artificially immunosuppressed before challenge to enhance susceptibility to FeLV infection and tumor develop- ment. Challenge virus was administered intranasally to ensure uniform exposure that conforms to the natural route of infection, and assures optimum delivery of challenge virus. Demonstrated safety is particularly critical in the case of an FeLV vaccine. Whole FeLV virus (or killed) contains a specific envelope protein, designated gp107, that is responsible for host immunosuppression.2–4,16,17 Hyperacute safety

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