

LYMPHOCYTE T-CELL IMMUNOMODULATOR

This product license is conditional. Efficacy and potency test studies are in progress.

DESCRIPTION

Lymphocyte T-Cell Immune Modulator is a single chain polypeptide. It is a strongly cationic glycoprotein, and is purified with cation exchange resin. Purification of protein from bovine-derived stromal cell supernatants produces a substantially homogeneous factor, free of extraneous materials. The bovine protein is homologous with other mammalian species and is a homogeneous 50 kDa glycoprotein with an isoelectric point of 6.5. The protein is prepared in a lyophilized 1 microgram dose. Reconstitution in sterile diluent produces a solution for subcutaneous injection.

MECHANISM OF ACTION

Lymphocyte T-Cell Immune Modulator is a potent regulator of CD-4 lymphocyte production and function. It has been shown to increase lymphocyte numbers and IL-2 production in animals. A field study in 23 cats with Elisa confirmed Feline Immunodeficiency Virus (FIV) disease, or Feline Leukemia Virus (FeLV) induced disease was performed. Animals were administered an initial three dose regimen by injection at days 0, 7, and 14 days. Subsequent doses were given monthly, or as needed. No other treatment was given.

There was a rapid and significant increase in lymphocyte counts. In cats that were severely anemic, there was a significant improvement in red cell counts. Seventeen of the cats in the study had clinical scores calculated before and after treatment, based upon the most common symptoms of FIV and FeLV disease. The improvement of symptoms based on clinical scores was significant after the three dose loading regimen. The long-term benefits of treatment have not been clinically established. However, there have been several long-term survivors receiving monthly injections, two of which became negative for virus using Polymerase Chain Reaction (PCR) testing on bone marrow aspirate biopsy.

INDICATIONS

Lymphocyte T-Cell Immune Modulator is intended as an aid in the treatment of cats infected with feline leukemia virus (FeLV) and/or feline immunodeficiency virus (FIV), and the associated symptoms of lymphopenia, opportunistic infection, anemia, granulocytopenia, or thrombocytopenia.

CONTRAINDICATIONS

There are no known contraindications for use of Lymphocyte T-Cell Immune Modulator. It is advised that concurrent use of corticosteroids diminishes the full effectiveness of the product.

DOSAGE AND ADMINISTRATION

Lymphocyte T-Cell Immune Modulator is administered by subcutaneous injection of 1 ml upon diagnosis of the presence of FIV or FeLV disease. Repeat with 1 dose at 7 and 14 days. Additional weekly treatments may be needed to maintain normal lymphocyte levels.

RECOMMENDATION

When Lymphocyte T-Cell Immune Modulator is used as an aid in the treatment of FeLV or FIV disease, monitoring of blood cell parameters, especially lymphocyte and red cell counts is recommended to evaluate the subject's progress. Following the initial three dose regimen (loading dose), subsequent injections may be given as necessary based upon blood results and symptoms.

Benefits of long-term treatment have not been clinically established. However, several animals in the field trial that received monthly or bimonthly injections have remained symptom free for long periods.

CAUTIONS

The effects of this protein have not been evaluated in pregnant or young animals. However, the low dosage and homology of this product among mammalian species, as well as, the absence of any observed adverse events in several animal species, suggests that the product has a very low toxicity profile.

HOW SUPPLIED

Lymphocyte T-Cell Immune Modulator is supplied in a box containing 10-1 dose vials of lyophilized product and 10-1ml vials of sterile diluent. Do not store over 45° F. Each vial of product contains 1 dose which is reconstituted with 1 ml of sterile diluent. After reconstitution, invert vial 2-3 times to insure complete dissolution. Use within 4 hours of reconstitution.

**LYMPHOCYTE T-CELL IMMUNOMODULATOR IS
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