FOR ANIMAL TREATMENT ONLY

EQUIMUNE®
MYCOBACTERIAL CELL WALL FRACTION
IMMUNOSTIMULANT

1 mg/mL Mycobacterial Cell Wall Fraction
Contains 30 mcg/mL Gentamicin as a preservative

An immunotherapeutic agent for use as an aid in the treatment of Equine Respiratory Tract Infections of viral origin.

Description:
Research has shown that mycobacterial cell wall compounds have immunomodulating activity. Equimune® is a sterile emulsion of purified mycobacterial cell walls which have been extracted by a process which reduces their toxic and allergic effects, but retains their immunostimulating activity.

Equimune® activates antigen presenting cells thereby enhancing the production of the polypeptide cytokine interleukin 1 (IL-1). The IL-1 molecule is one of the body's natural adjuvants, and therefore nonspecifically amplifies the immune response to antigens. This amplification includes both cell mediated immunity (CMI) and humoral antibody (HA) responses. IL-1 intensifies the CMI response by inducing the proliferation of cytotoxic lymphocytes (Tc), augmenting the phagocytic abilities of monocytes and macrophages, and by activating cytokine production. IL-1 also acts directly on the hypothalamus to induce a fever which then enhances the function of T lymphocytes. Proliferation of fibroblasts is induced by IL-1 and thus IL-1 production aids in the wound healing processes. Wound healing processes are further augmented by the increased phagocytic action of macrophages and monocytes. This is important in overcoming alveolar cell damage caused by respiratory disease.

Cell mediated immunity plays a major role in resistance to, and recovery from, viral infection such as influenza virus and herpesvirus infections including equine herpesvirus. Immunotherapy trials conducted in Canada and elsewhere have indicated a positive response in horses with viral respiratory tract infections. Mycobacterial cell wall preparations have been shown to increase the number of alveolar macrophages in animals and to stimulate the release of IL-1 from these cells. Mycobacterial Cell Wall Fraction Immunostimulant has been shown to cause the transformation of Lymphocytes previously sensitized by viruses.

DIRECTIONS FOR USE:

FOR USE ONLY BY, OR UNDER THE DIRECTION OF, A REGISTERED VETERINARY SURGEON.
FOR INTRAVENOUS USE ONLY

Horses with a history of hyper-immune disease (vaccine bumps, allergies, etc.) should be closely monitored, by a veterinarian. In the event of urticaria, edema, pneumonitis or persistent fever, treat appropriately. Do not repeat treatment with Equimune® in horses which develop these symptoms.

Many factors influence the efficacy of immunotherapy in animals. Concurrent disease, stresses due to shipping or weaning, nutritional status, parasitism, environmental conditions and concurrent therapeutic regimens are important considerations.

Dosage and Administration:

1. It is important to ensure that the emulsion remains thoroughly mixed during injections. Shake vial gently, roll between hands, or heat under 65°C water to assist emulsification. Air space has been provided in the vial to facilitate mixing. Inject using a disposable syringe and a 21G x 1.5” disposable needle.
2. Use entire contents when first opened. Discard remaining portions.
3. Observe aseptic techniques when injecting animals.

The recommended dose for immunostimulation is 1.5 mL by intravenous injection into the jugular vein. Treatment may be repeated in one to three weeks. For best results, Equimune® should be administered at the first clinical signs of equine respiratory tract infections of viral origin.

Precautions:

1. In the event of an anaphylactic reaction, administer adrenaline.
2. KEEP OUT OF REACH OF CHILDREN.
3. Immune stimulation regimens have the potential to stimulate hypersensitivity reactions. These may be manifested as a persistent fever, with or without pulmonary involvement. Veterinary attention should be sought if these symptoms occur.
4. Contains 30 mcg/mL Gentamicin as a preservative.
Safety: In field use, there have been no reported adverse effects with pregnant mares. Other than the contraindications listed below, Equimune® is compatible with standard treatment and vaccination regimens.16

Contraindications: Cortisone reduces the production of IL-1.1 Concurrent use of corticosteroids, ACTH and other products known to be immunosuppressive is not recommended.

Side Effects: Mild fever, drowsiness, and an increased metabolic rate leading to decreased appetite may occur for one to two days following an Equimune® injection. These are normal responses to the release of IL-1,1,6 An elevated body temperature enhances the immune function by stimulating lymphocyte activity,2,17 and thus is not an adverse side effect.

MEAT WITHHOLDING PERIOD (HORSES): DO NOT USE less than 28 days before slaughter for human consumption.

Disposal: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled “sharps” container. The container should be of a type to reduce the possibility of injury to handlers during collection and disposal. Incineration is the preferred method of disposal, otherwise “sharps” should be buried at a suitable site, such as an on-farm chemical disposal pit located away from watercourses.

Storage: Store between 2°C and 8°C (Refrigerate. Do not freeze.) APVMA Approval No. 51105/06194

Presentation: Equimune® is packaged in 1.5 mL single dose vials.

References:

APVMA Approval No. 51105/0903

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