For Veterinary Use Only

MYCOBACTERIUM CELL WALL FRACTION IMMUNOSTIMULANT IMMUNOCIDIN®

Description and Action: The *Mycobacteriaceae* have been known for many years to have antitumor activity. **Immunocidin®** is an emulsion of mycobacterial cell wall fractions that have been modified to reduce their toxic and allergic effects, but retain their antitumor activity. **Immunocidin®** stimulates the activation of macrophages and thymic lymphocytes which kill tumor cells.

Indications: **Immunocidin®** is recommended for the immunotherapy of mixed mammary tumor and mammary adenocarcinoma in dogs. Although **Immunocidin®** is administered by intratumoral injection, the response is generalized, and untreated sites frequently undergo regression. Prognosis should be guarded in advanced malignant disease with metastases, as remissions will be less frequent. Remissions cannot be guaranteed as each tumor will vary in its response.

Adverse Reactions: Mild fever, drowsiness, and an increased metabolic rate leading to decreased appetite may occur for one to two days following an **Immunocidin®** injection. Local inflammation which is sensitive to the touch occurs fairly often but it usually is not bothersome to the patient. Necrosis with suppuration may occur in regressing tumors and clients should be informed that the tumor may drain for several weeks. Tumors may be aspirated with a sterile syringe and needle to help prevent drainage. If drainage develops, it often may be stopped by application of astringents such as silver nitrate and styptic powders.

Contraindications: Immunotherapy may not be as effective in animals receiving concurrent immunosuppressive therapies. Avoid the use of corticosteroids or ACTH where possible.

Caution: The inflammatory response with edema and malaise occasionally is severe after the initial treatment. Therapy should be discontinued until the reaction has subsided. Animals with a history of hyper-immune disease (vaccine bumps, allergies, etc.) should be closely monitored. In the event of urticaria, lymphadenitis, cellulitis, or abscessation, treat appropriately. Discontinue **Immunocidin®** therapy in animals which develop these signs.

Administration and Dosage: **Immunocidin®** is administered only by intratumoral injection. The entire tumor and a small region of adjacent and underlying tissue must be thoroughly infiltrated using no larger than a 20-gauge needle. Injection without careful infiltration of the tumor may not be effective. It is important to mix the emulsion thoroughly and inject the tumor as quickly as possible because the emulsion may begin to separate soon after mixing. The tumor tissue may be very firm and excessive pressure on the syringe plunger may be required to infiltrate the tumor. The injection may produce pain in some animals; anesthetics or additional analgesics may be used. Dosage varies with tumor size but 1 mL should be considered a minimum dose.

Immunocidin® proved to be effective against mixed mammary tumors and mammary adenocarcinomas in dogs. Canine mammary tumors may be treated once, 2 to 4 weeks prior to surgery. Whereas surgical removal of mammary tumors produces a desirable cosmetic result, tumor-free survival is not significantly improved. **Immunocidin®** is well tolerated by aged dogs with chronic cardiovascular and renal disease. This makes immunotherapy without surgery an attractive method of treatment for those patients that are poor surgical risks. Treatment should be repeated every 1 to 3 weeks. Tumors that fail to respond after 4 treatments should be considered refractory and therapy discontinued. Eighty-eight percent of dogs treated with immunotherapy only were free of tumor two years later. Individual doses range from 1 to 30 mL (average about 2.5 mL). The average cumulative dose is about 10 mL.

Precaution: Store at 36–45°F (2–7°C) in a refrigerator but do not freeze. The emulsion separates on standing. Resuspend by shaking or rotating the vial between the hands until the emulsion has a homogeneous "milky" appearance. Use entire contents when first opened. This product contains gentamicin as a preservative. KEEP OUT OF REACH OF CHILDREN.

Packaging: Contains 1 x 2.5 mL vial

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