

## QUESTIONS AND ANSWERS

### 1. What is Immunocidin™?

Immunocidin™ is a veterinary biologic for the treatment of canine mixed mammary tumours and mammary adenocarcinomas. It is based on Bioniche Life Sciences' proprietary mycobacterial cell wall technology platform. The biologically active component of Immunocidin™ is the mycobacterial cell wall (MCW) fraction derived from non-pathogenic *Mycobacterium phlei*. Immunocidin™ is an oil emulsion containing 1 mg per mL of the active ingredient.

### 2. How does MCW Fraction Work?

Cell wall fractions of *Mycobacterium phlei* have a dual (indirect and direct) anticancer mode of action. They exert indirect anticancer activity by stimulating macrophages and lymphocytes leading to the release of anti-tumour cytokines. In addition, *Mycobacterium phlei* cell wall fractions act directly by inducing apoptosis of cancer cells.

### 3. How is Immunocidin™ Administered?

Immunocidin™ is administered only by intratumoural injection. Carefully and thoroughly infiltrate the tumour. Avoid intravascular injection. Larger tumours may require more than one needle stick to infiltrate the entire mass. The injection may produce pain in some animals; sedation or analgesics may be required. The emulsion separates on standing; it is important to mix it thoroughly prior to administration. Shake or rotate the vial until the emulsion has a homogeneous "milky" appearance.

### 4. What is the dose of Immunocidin™?

Dosage varies with tumour size, but generally 0.2 mL to 2.5 mL is administered per treatment (in dogs with more than one tumour, total dose is divided among tumours). 1 mL should be considered a minimum dose for the average dog; however, dose may be adjusted down (0.2 mL to 0.5 mL) for geriatric and smaller dogs.

### 5. How many treatments should be given?

Most dogs require three to four treatments. Tumours that fail to respond after four treatments should be considered refractory, and therapy discontinued.

### 6. How frequently should treatments be given?

Treatments should be repeated every one to three weeks.

## 7. What treatment protocols are recommended?

- Immunocidin™ as the sole treatment with administrations at one to three week intervals.
- Pre-operative Immunocidin™ treatment two to four weeks prior to surgical excision.
- Treatment two to four weeks post-operatively to reduce the risk of recurrence and metastatic disease.

## 8. Are there any adverse reactions which may occur following administration?

Mild fever, drowsiness, and an increased metabolic rate leading to decreased appetite may occur for one to two days following an Immunocidin™ injection. These are all normal responses to the release of cytokines. Local inflammation (marked swelling and pain) often occurs following treatment, and may require the use of analgesics. Therapy should be discontinued until the reaction has subsided. Necrosis with suppuration often occurs in regressing tumours and clients should be informed that the treated area may drain for several weeks.

## 9. Are there any contraindications?

Immunocidin™ will not be as effective in animals receiving concurrent immunosuppressive therapies. Avoid the use of corticosteroids or ACTH where possible.

## 10. How is Immunocidin™ supplied?

Immunocidin™ is supplied as 2.5 mL vials.

## 11. What are the storage requirements?

Immunocidin™ should be refrigerated (2 – 7 °C). This product contains gentamicin as a preservative.

## 12. How effective is Immunocidin™ for the treatment of canine mammary tumours?

The study found that 88% of dogs treated with mycobacterial cell wall fraction immunostimulant for mammary cancer were tumour-free two years later. Prognosis should be guarded in cases of advanced malignant disease with metastasis.



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