Moxidectin Drug Residue Trial

Dave Lawrence

Abstract

Moxidectin Injection is not registered for use in deer and therefore has a default 91day withholding time. A trial on 5 deer showed moxidectin residues at 49days post injection were clear of MPLs. Guidance for the trial was provided by NZFSA. Veterinarians can confidently advise farmers re off label use of Moxidectin Injection. Veterinarians need to meet their obligations as per Discretionary Use in the Code of Professional Conduct.

Keywords

Withholding Time, Moxidectin Injection, deer, moxidectin tissue residues, off label use.

Introduction

The Agricultural Compounds and Veterinary Medicines (ACVM) Act provides for the use of agricultural compounds in food producing animals. Under the Act products are registered for use in specified animals and to meet the requirements of the Act. These agricultural compounds must not result in breaches of domestic food residue standards. Hence products are registered with a Withholding Time (WT) from treatment to slaughter.

Data required to support a WT registration normally requires sampling of five different tissue sites from at least 5 animals. This is repeated over serial time frames to determine a trend. All samples must be sent to and tested by an Approved Laboratory

Background

Moxidectin as a Pour On (Cydectin Pour On) is registered for use in deer and has a nil meat WT. In recent times moxidectin injection has found increasing favour for use in deer. Moxidectin injection (Cydectin Inj) is not registered for use in deer and as such has a default WT of 91days. The purpose of this trial is not intended to determine an official label claim WT for moxidectin injection. The purpose is to provide a recommended WT based on sound science to enable veterinarians and their farmer clients to use moxidectin injection at less than 91dys but greater than 49dys from slaughter.

Material and methods.

Five Wapiti cross rising one year deer were selected on a commercial deer farm in Southland. The co-operation of the processor and NZFSA was sought and received. Selection of animals was based on their being at a desired killable weight at slaughter. All 5 deer were tagged and injected subcutaneously with Moxidectin injection at 0.2mg moxidectin/kg liveweight.

49dys post treatment they were sent to slaughter at a local DSP.

Samples were collected based on advice from NZFSA. Liver and fat (omental) samples were collected from each of the five deer. Labelled samples were packaged in an approved secure manner and dispatched to the approved laboratory (AsureQuality Laboratory Wellington). Pending the results of moxidectin tissue residue analysis all carcasses were held in "detain"

Results

The results of the tissue analysis are presented in the official Certificate of Analysis below

The MPL of Moxidectin in Deer fat is 0.5mg/kg

The MPL of Moxidectin in Deer Liver 0.1mg/kg

49dys after moxidectin inj all 5 liver samples were clear = below LOD 0.001mg/kg.

Four fat samples were clear = below LOD 0.0014mg/kg and in one fat sample moxidectin was detected 0.0042mg/kg. **This is 120x less than the MPL**

All carcasses were released as eligible for export.

Certificate of Analysis

Date Issued:

18 November 2010

Client:

Elk and Wapiti Society of New Zealand

317 Bluff Road RD 1 Sheffield Canterbury 7580 New Zealand

Attention:

Dave Lawrence

Copies to:

Susan Morris (NZFSA) Tracey McLean (EWSNZ)

Date received:

05 November 2010

AsureQuality Lab. Reference:

83690-1 to -10

Customer Reference Number:

EWSNZ Trial 2 SFF

Sample Type:

Cervine Liver, Cervine Fat

Analysis:

Moxidectin

Methods:

WC-006 (EIV-04) WC-193 (ESA-01)

Comments:

Liver samples were extracted as per the in-house method WC-006 "Determination of Macrocyclic Lactones in Tissue by High Performance Liquid Chromatography with Fluorescence Detection (HPLC-FL)".

Fat samples were extracted as per the in-house method WC-193 "Determination of Macrocyclic Lactones and Monepantel in Fat by LC-MS/MS".

Results are reported in milligrams per kilogram (mg/kg) to 2 significant figures and are corrected for recovery.

Unless requested, samples will be disposed of eight weeks from the date of this report.

Gayle Holmes

Team Leader GLP/Forensics AsureQuality Limited

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Test Results

Laboratory Reference: 83690

Date Received: 05 Nov 2010

Date Extracted: 10 & 11 Nov 2010 Sample Condition: Acceptable

Laboratory ID	Animal ID	Matrix	Moxidectin (mg/kg)
83690-1	2773652-1953	Fat	ND
83690-3	2773652-1941	Fat	ND
83690-5	2773652-1942	Fat	ND
83690-7	2773652-1922	Fat	ND
83690-9	2773652-1943	Fat	NQ (0.0018)

Detection Limits:

Compound	Matrix	Method	LOD (mg/kg)	LOQ (mg/kg)
Moxidectin	Fat	ESA-01	0.0014	0.0042

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	Laboratory Analysts:	Anita Corderoy	Checked By:	Ian Jackson

Laboratory ID	Animal ID	Matrix	Moxidecti	in (mg/kg)
83690-2	2773652-1953	Liver	ND	
83690-4	2773652-1941	Liver	ND	
83690-6	2773652-1942	Liver	ND	
83690-8	2773652-1922	Liver	ND	
83690-10	2773652-1943	Liver	ND	
Detection Limits:				
Compound Moxidectin	Matrix Liver	Method EIV-04	LOD (mg/kg) 0.001	LOQ (mg/kg) 0.002
Tioniace				33.1.373
Laboratory Analysts:	Anita Corderoy		Checked By:	Ian Jackson

Discussion

The trial provides unequivocal evidence that deer treated with Moxidectin by s/c injection at the cattle dose rate are safe to send to slaughter 49days after treatment.

Veterinarians can confidently advise clients of this but must ensure they have met the requirements for "Off-label" use of a registered veterinary product.

The VCNZ statement The Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians sets out VCNZ expectations in relation to using or authorising these types of products.

Section 2.a) (i) states

Veterinarians must meet all of the requirements of consultation Section 2. b) (i) states

- Ensure that the following information is conveyed to the animal's owner or agent, in writing, and that a record is kept by the prescribing veterinarian:
 - Name of owner or owner's agent;
 - The identity of the animal/group to be treated;
 - The trade name of the drug, the active ingredient if compounded, and the concentration;
 - The dose rate and frequency of treatment;
 - The route and method of administration;
 - The duration of treatment;
 - The withholding time;
 - The date of treatment;
 - The name of the prescribing veterinarian and the name, address and contact phone numbers of that veterinarian's practice.

MAF requires records to be kept for inspection for two years

The crucial aspects are that as per the trial moxidectin injection was by subcutaneous injection at 0.2mg/kg at >49days from slaughter

All stock going to slaughter are accompanied by an Animal Status Declaration ASD Form. Based on a veterinary consultation your farmer client **does not** need to declare using moxidectin injection 49 days from slaughter on the ASD.

Processors and NZFSA will accept these deer as safe and eligible for export markets.

Acknowledgements

Elk and Wapiti Society of New Zealand, MAF Sustainable Farming Fund, NZFSA (Susan Morris, Mike Claire), Pfizer (Victoria Chapman), Silver Fern Farms Kennington, Asure Quality Lab Wellington and the deer farmer