

Australian Sheep Veterinarians

a special interest group of Australian Veterinary Association Ltd

ABN 63 008 522 852



10 March 2016

Scientific Assessment and Chemical Review
Residues and Trade
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Via email to: enquiries@apvma.gov.au

Dear Sir/Madam

Re: LACTATION RESTRAINT: Metacam 20mg/ml Solution for Injection.

The Australian Sheep Veterinarians (ASV) is a special interest group of the Australian Veterinary Association (AVA).

The ASV executive considered the TRADE ADVICE NOTICE published by the APVMA on Metacam 20mg/ml Solution for Injection, dated February 2016, at its meeting on 26 February 2016.

We strongly endorse the registration of such a product, and after considering the purpose for which it is intended, have no issues with the meat WHP. However, we consider the label restraint '*DO NOT USE in ewes which are producing or may in the future produce milk that may be used or processed for human consumption*' to be inappropriate and unreasonable.

We also draw attention to this wording as being misleading and/or confusing on many products used in the sheep industry on which it appears as a restraint. It limits veterinarians when prescribing or recommending such products under jurisdictional control of use regulations, even if a risk assessment provides assurance that violative residues will not occur from such use.

The incongruity of this situation is evident considering that a veterinarian may prescribe an unregistered veterinary chemical or a registered chemical off-label for such animals when no such mandatory restraint exists, but is prohibited from prescribing contrary to this stated restraint, even when this has no reasonable scientific basis.

It is recommended that label restraints should be based upon an actual assessment of risk which includes the likelihood of use of a registered veterinary chemical or active ingredient resulting in a violative residue in milk beyond a specified time period, rather than on a precautionary prohibition on the use of a product without reasonable finite limits.

The current precautionary label requirement in respect to lactation, limits the subsequent potential for ewes to be used in a dairy and the availability of sheep for such purposes, irrespective of whether it could be assessed that there is little to zero likelihood of residues. This is an unreasonable barrier to both trade and appropriate use of animals for commercial purposes. Considering the welfare imperative for pain relief in aversive husbandry procedures, this restraint has further unintended detrimental consequences. It will mean that tail docking and disbudding of any lamb intended for later dairy use as an adult, will have to be performed without pain control. Given the tissue residue data for this product, it is hard to make a case that an adult lactating ewe who received meloxicam for tail docking and disbudding when she was a lamb, could be a milk residue risk.

Australian Sheep Veterinarians
Garden City Office Park
Building 3/2404 Logan Road
Eight Mile Plains QLD 4113

P · 07 3422 5302
F · 07 3423 1503
E · acv@ava.com.au
W · asv.ava.com.au

Australian Sheep Veterinarians

a special interest group of Australian Veterinary Association Ltd

ABN 63 008 522 852



We consider that any restraint in respect to lactation must be based upon finite time limits rather than on what appears to be an inappropriate application of the precautionary principle, unless the APVMA can present pharmacological evidence of chemical residues in dormant mammary tissue being excreted in milk during subsequent lactations, or persistence of chemical residues in milk beyond a reasonable WHP. If a standard time were applied, this could be modified if a particular formulation or active presented a specific risk profile.

We understand that New Zealand and other countries apply time limits in relation to administration of a veterinary chemical when milk is to be or being produced, and we urge the APVMA to adopt this risk-based approach.

Yours sincerely

Bruce Watt

President

Australian Sheep Veterinarians



Australian Sheep Veterinarians
Garden City Office Park
Building 3/2404 Logan Road
Eight Mile Plains QLD 4113

P · 07 3422 5302
F · 07 3423 1503
E · acv@ava.com.au
W · asv.ava.com.au