



From:

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Re: Amprol® 25% Feed Mix, BMD® 110 G
Case Id: ON-061019-20088
Date of Response: Jun 11, 2019 12:50:16 PM

Case Information:

Date Submitted Jun 10, 2019 4:42:10 PM
Species Chickens/Layers
Number of Animals 113503
Location of Animals Ontario
Reason for Use Treatment
Additional Information Layer pullets at 11 1/2 weeks with coccidiosis and necrotic enteritis.
Drugs Administered

Drug Trade Name	Generics	Route	Dose	Diseases
Amprol® 25% Feed Mix	• amprolium	Oral - Feed	125 ppm (in feed) Continuously for 14 days	• Alimentary: coccidiosis
BMD® 110 G	• bacitracin methylenedisalicylate	Oral - Feed	110 ppm (in feed) Continuously for 14 days	• Alimentary: necrotic enteritis - clostridium perfringens

Response and Recommendation: 24 hours for meat and eggs.

In Canada, amprolium is approved for use in broiler chicken feeds up to 250 ppm with a zero withdrawal time but the product labeling has a warning that this product should not be fed to laying birds in production. Amprolium does cross into the egg yolk and white. The legal Canadian maximum residue limit (MRL) is 7 ppm for whole egg, while in the United States (both their in water and in feed products are labelled for layers with a zero withdrawal time) the tolerance is 8 ppm in the yolk and 4 ppm in the whole egg. From published research, amprolium was fed to

layers at up to 250 ppm and residues in yolk never exceeded the United States tolerance. Therefore, given that the United States products are labelled with no egg withdrawal time and their tolerance in whole egg is lower than the Canadian MRL, we cannot see a valid scientific reason to recommend a withdrawal interval for the use of the amprolium premix formulation in layers. Bacitracin is currently labelled for use in broiler chicken rations for the prevention of necrotic enteritis at 55 ppm to be fed continuously until birds reach market weight. Bacitracin is also labelled at 110 ppm but only up to 1 week of age for reduction of early mortality due to diminished feed consumption and chilling. According to the CMIB, no withdrawal period is required when fed according to the label directions (<http://www.inspection.gc.ca/animals/feeds/medicating-ingredients/mib/bacn-m/eng/1331046058400/1331046119651>). The CMIB has also now included this statement regarding bacitracin: "This livestock feed contains a medically important antibiotic. To reduce the development of antimicrobial resistance and maintain effectiveness, use this antibiotic prudently and for the shortest duration required to achieve the desired clinical outcome." Therefore, the addition of bacitracin at 110 ppm time periods beyond the first week of age is an extralabel drug use of a medically important antibiotic. So in keeping with the Canadian gFARAD policy of recommending a 'greatly extended' withdrawal interval for extra-label drug use, we have recommended a meat withdrawal interval of at least 24 hours for the use of bacitracin in chickens at doses of 110 ppm beyond the first week of age. Bacitracin is poorly absorbed from the gastrointestinal tract and the distribution to organs and tissues is negligible. In the United States, bacitracin is approved for use in broiler chickens at concentrations of 4.4- 55 ppm and 220 ppm and in layer chickens at concentrations of 11- 27.5 ppm with no stated meat or egg withdrawal time. The Canadian MRL for bacitracin in chicken tissues is 0.5 ppm (kidney, liver, muscle, and skin & fat) which is the same as the United States. In the United States, the MRL for bacitracin in eggs is also 0.5 ppm. However, there is no MRL established for bacitracin in eggs in Canada. Since bacitracin is not approved for use in layers and since there is no MRL in eggs in Canada and to comply with the Canadian gFARAD policy of recommending a "greatly extended" withdrawal interval for extralabel drug use, we recommend following a minimum 24 hours egg withdrawal interval for this use of bacitracin in laying hens. We are not aware of any interaction between these drugs that would require further extension of the withdrawal intervals. Therefore, we recommend following a withdrawal interval of at least 24 hours for meat and eggs for this combination.

Therefore, the Canadian gFARAD recommends a withdrawal interval of 24 hours for meat and eggs, which should be sufficient so that detectable residues are not found. Furthermore, this recommendation for residue avoidance does not address the risks of developing or transmitting antimicrobial resistance from treated animals to other animals or humans following the extralabel use of this antimicrobial. Because the Canadian gFARAD withdrawal recommendation is not an official withdrawal time and is based on data that has not been reviewed nor approved by the Veterinary Drugs Directorate or the Canadian Food Inspection Agency, responsibility for residue violations rests with the attending veterinarian.

To review this request in CgFARAD:

<https://farad.usask.ca/cgfarad/vet/viewRequest?id=20088&langen>