

From:

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To:
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Re: Chlor 100 Premix, BMD® 110 G

Case Id: ON-081321-23468

Date of Response: Aug 16, 2021 8:17:37 AM

Case Information:

Date Submitted Aug 13, 2021 11:40:19 AM Species Chickens/Broiler Breeder

Number of Animals 11000

Location of Animals Reason for Use

Additional Information Please provide meat and egg withdrawal recommendations.

Drugs Administered

Drug Trade Name	Generics	Route	Dose	Diseases
Chlor 100 Premix	 chlortetracycli ne 	Oral - Feed	110 ppm (in feed) Continuously for 14 days	 Alimentary: colibacillosis
BMD® 110 G	bacitracin	Oral - Feed	55 ppm (in feed) Continuously for 14 days	Alimentary: necrotic enteritis - clostridium perfringens

Response and Recommendation: 8 days for meat and 24 hours for eggs

Chlortetracycline was approved for use in broiler chickens at doses up to 220 ppm with a 7 day meat withdrawal time. It was also approved for layer chickens at doses up to 110 ppm with no stated egg withdrawal time on the label implying that the egg withdrawal time was zero at these doses. Recent changes in legislation removed all growth promotion claims on feed additive drugs in Canada. These changes resulted in no "on label" claims for oxytetracycline or chlortetracycline in any class of chickens. With the old labelling, oxytetracycline and chlortetracycline were

approved for layer hens with no egg withdrawal times based on maximum residue limits (MRLs) in eggs of 0.4 ppm. With the updated CMIB and drug labelling, any use of oxytetracycline or chlortetracycline in feed in chickens, including layer hens, is now extra label drug use (ELDU). In concurrence with the US codified regulations regarding ELDU, CgFARAD™ has a policy of recommending a "greatly extended" withdrawal interval when drugs are used extra label in food producing animals. Therefore, CgFARAD™ will now recommend an 8 day meat withdrawal interval and a 24 hour egg withdrawal interval for oxytetracycline or chlortetracycline administered at concentrations consistent with the old approved labelling. Bacitracin is 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 has just been approved for the treatment of necrotic enteritis in broiler and layer chickens at 110 ppm to be fed continuously for 7 days (https://health-products.canada.ca/dpd-bdpp/dispatch-

repartition.do;jsessionid=C53EDE6E4C0A043660B75BA6CBA010EF). The label does not mention any adverse effects in broiler breeder chickens. According to the updated label, no meat or egg withdrawal period is required when fed according to the label directions. The CMIB has 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 55 ppm for durations longer than 7 days in layer chickens is an extralabel drug use of a medically important antibiotic. So, in keeping with CgFARAD™ policy of recommending a "greatly extended" withdrawal interval for extralabel drug use in food animals, we recommend following a withdrawal interval of at least 24 hours for eggs for this use of bacitracin. For meat, we recommend following a zero day withdrawal interval as this is a label dose. 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 8 days for meat and 24 hours for eggs for this combination.

Therefore, the Canadian gFARAD recommends a withdrawal interval of 8 days for meat and 24 hours for 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.