



From:

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To: [REDACTED]	Re: Monensin Premix, Flavomycin® 4
Telephone: [REDACTED]	Case Id: ON-112521-23938
Fax: [REDACTED]	Date of Response: Nov 25, 2021 10:32:29 AM
Email: [REDACTED]	

Case Information:

Date Submitted Nov 25, 2021 9:52:02 AM
Species Turkeys
Number of Animals 12000
Location of Animals
Reason for Use Prophylaxis

Drugs Administered

Drug Trade Name	Generics	Route	Dose	Diseases
Monensin Premix	• monensin sodium	Oral - Feed	100 ppm (in feed) Continuously for 14 days	• Alimentary: coccidiosis
Flavomycin® 4	• bambarmycins	Oral - Feed	6 ppm (in feed) Continuously for 14 days	• Alimentary: necrotic enteritis - clostridium perfringens

Response and Recommendation: 48 hours

Monensin is approved for inclusion in turkey rations for the prevention of coccidiosis at 100 ppm with no limit to the duration of treatment and with a zero-day withdrawal time. Flavomycin is labeled “for increased rate of weight gain” in turkeys up to 12 weeks of age at 2 ppm of bambarmycins in feed with a zero day withdrawal time. Your dose of flavomycin is 3X the approved dose in turkeys. By convention, we add an elimination half-life for every increasing/doubling of the drug dose. Data on withdrawal information is not readily available from any of the US databases. However, studies based on bovine tissues lead the FDA to conclude a

zero withdrawal time for bambermycins because no residues are found in any tissue after bambermycins is fed at many times the approved dose. Given that the label withdrawal time of flavomycin is zero days and to comply with CgFARAD™ policy of recommending a “greatly extended” withdrawal interval for extralabel use of drugs in food animals, we have previously recommended a withdrawal interval of at least 24 hours when flavomycin was used in turkeys at 2X the recommended dose. For your use of flavomycin at 6 ppm in turkeys up to 12 weeks of age, we would recommend extending the above recommendation to at least 48 hours. 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 48 hours for this combination.

Therefore, the Canadian gFARAD recommends a withdrawal interval of 48 hours, 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.