

NADA Number: 048-761	
Trade Name	Aureomycin® 90 Granular Aureomycin® 100 Granular Aureomycin® 50 Granular Aureomycin® Type A Medicated Article
Sponsor	Alpharma, Inc.
Ingredients	Chlortetracycline
Species	Swine, breeding swine Cattle, dairy, not lactating Cattle, beef Sheep, growing Turkey, growing Cattle, calves, excluding veal calves Turkey, not laying eggs for human consumption Turkey, poults, under 4 weeks age Sheep, breeding Duck, excluding laying eggs for human consumption Psittacine Chicken, not laying eggs for human consumption Swine, no use class stated or implied Swine, growing
Routes of Administration	Per Os
Dose Form	Medicated feed Type B medicated feed
Drug Form	Type A Medicated Article Type B medicated feed
Dispensing Status	OTC
Exclusivity	Granted for use in chickens producing eggs for human consumption Granted for use as administered as a top dressing for treatment in cattle of bacterial enteritis caused by Escherichia coli and bacterial pneumonia caused by Pasteurella multocida organisms susceptible to chlortetracycline. Exclusivity is granted based on a supplemental approval for the use of an approved Type A Medicated Article containing chlortetracycline to formulate a free-choice loose mineral Type C medicated feed (containing 6000 grams chlortetracycline per ton of feed) for beef and non-lactating dairy cattle. Granted for the free-choice feeding to grazing beef cattle weighing over 700 lbs at .0125 to .05 lb of Type C feed per 100lb of body weight per day for control of Anaplasma marginale.

558.128 Chlortetracycline.

Specifications: Type A medicated article containing the following concentrations of either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride, or, for products intended for use in milk replacer chlortetracycline hydrochloride.

Conditions of use:

Chickens

Amount: 10-50 grams per ton of feed.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: No limitations are included in the CFR for this species when using this product in this amount.

Amount: 100-200 grams per ton of feed.

Indications: For the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

Limitations: Feed continuously for 7 to 14 days.

Amount: 200-400 grams per ton of feed.

Indications: For the control of chronic respiratory disease and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.

Limitations: Feed continuously for 7 to 14 days.

Amount: 500 grams per ton of feed.

Indications: For the reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline.

Limitations: Feed for 5 days.

Turkeys (growing)

Amount: 10-50 grams per ton of feed.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: Do not feed to turkeys producing eggs for human consumption.

Turkeys

Amount: 200 grams per ton of feed.

Indications: For the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

Limitations: Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.

Amount: 400 grams per ton of feed.

Indications: For the control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline.

Limitations: Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.

Amount: 25 milligrams per pound of body weight per day.

Indications: For the control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

Limitations: Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.

Turkeys (poults not over 4 weeks of age)

Amount: 400 grams per ton of feed.

Indications: For the reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.

Limitations: Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption.

Ducks

Amount: 200-400 grams per ton of feed.

Indications: For the control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

Limitations: Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 days. Do not feed to ducks producing eggs for human consumption.

Psittacine birds (cockatoos, macaws, and parrots)

Amount: 10 milligrams per gram of finished feed daily.

Indications: Suspected or known to be infected with *Chlamydia psittaci* sensitive to chlortetracycline.

Limitations: Feed continuously for 45 days. Each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. Warning: "Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials."

Dosage Amount,
Indications
& Limitations

Swine (growing)

Amount: 10-50 grams per ton of feed.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: No limitations are included in the CFR for this species when using this product in this amount.

Swine

Amount: 50-100 grams per ton of feed.

Indications: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by group E Streptococci susceptible to chlortetracycline.

Limitations: No limitations are included in the CFR for this species when using this product in this amount.

Amount: Feed approximately 400 grams per ton of feed, varying with body weight and feed consumption to provide 10 milligrams per pound of body weight per day.

Indications: For the treatment of bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline.

Limitations: Feed for not more than 14 days.

Swine (breeding)

Amount: 400 grams per ton of feed.

Indications: For the control of leptospirosis (reducing the instances of abortion and shedding of leptospirae) caused by Leptospira pomona susceptible to chlortetracycline.

Limitations: Feed continuously for not more than 14 days.

Sheep (growing)

Amount: 20-50 grams per ton of feed.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: No limitations are included in the CFR for this species when using this product in this amount.

Sheep (breeding)

Amount: 80 milligrams per head per day in feed.

Indications: For reducing the incidence of (vibrionic) abortion caused by Campylobacter fetus infection susceptible to chlortetracycline.

Limitations: No limitations are included in the CFR for this species when using this product in this amount.

Cattle (calves, up to 250 pounds)

Amount: 0.1 milligrams per pound of body weight per day in feed.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: In milk replacers or starter feed. Include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."

Amount: 10 milligrams per pound of body weight in feed.

Indications: Treatment of bacterial enteritis caused by E. coli susceptible to chlortetracycline.

Limitations: In milk replacers or starter feed. Include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."

Cattle (calves, 250-400 pounds)

Amount: 25-70 milligrams per head per day of feed.

Indications: For an increased rate of weight gain and improved feed efficiency in calves weighing 250-400 pounds.

Limitations: Include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in pre-ruminating calves. Do not use in calves to be processed for veal."

Cattle (growing, over 400 pounds)

Amount: 70 milligrams per head per day in feed.

Indications: For an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.

Limitations: Include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in pre-ruminating calves. Do not use in calves to be processed for veal."

Cattle (beef)

Amount: 350 milligrams per head per day.

Indications: For the control of bacterial pneumonia associated with shipping fever complex susceptible to chlortetracycline.

Limitations: Withdraw 48 hours prior to slaughter.

Cattle (beef, under 700 pounds)

Amount: 350 milligrams per head per day.

Indications: For the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

Limitations: Withdraw 48 hours prior to slaughter.

Cattle (beef, over 700 pounds)

Amount: 0.5 milligrams per pound of body weight per day in feed.

Indications: For the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in beef cattle over 700 pounds.

Limitations: No limitations are included in the CFR for this species when using this product in this amount.

Cattle (calves, beef, nonlactating dairy)

Amount: Feed 4,000 to 20,000 grams per ton of feed.

Indications: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

Limitations: As a top dress vary with body weight and feed consumption to provide 10 milligrams per pound per day. Treat for not more than 5 days. In milk replacers or starter feed; include on labeling the warning: "A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal."

Cattle (beef and non-lactating dairy)

Amount: 6,000 grams per ton of feed as a free-choice, loose mineral Type C feed as follows:

-----	Ingredient	Percent	International Feed
No. -----	Dicalcium Phosphate	46.20	
6-26-335	Sodium Chloride (Salt)	15.00	6-04-152
	Magnesium Oxide	10.67	
6-02-756	Cottonseed Meal	10.00	5-01-625
	TraceMineral/Vitamin	3.80
	Premix* Calcium Carbonate	3.50	6-01-069
	Dried Cane Molasses	3.00	
4-04-695	Potassium Chloride	2.00	6-03-755
	Mineral Oil	2.00	8-03-123
	Iron Oxide	0.50	6-02-431
	Chlortetracycline	3.33
	Type A medicated article		
	(90 gram/lb)		-----

* Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

Indications: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

	<p>Limitations: Feed continuously on a free-choice basis at a rate of 0.5 to 2.0 milligrams of chlortetracycline per head per day.</p>
Tolerances	<p>Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and duck or 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.</p> <p>A tolerance is established for residues of chlortetracycline in eggs of 0.4 part per million.</p>