

Date of Approval Letter:

JAN 24 2002

## FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 048-761

AUREOMYCIN<sup>®</sup> 50 Granular, AUREOMYCIN<sup>®</sup> 90 Granular,  
and AUREOMYCIN<sup>®</sup> 100 Granular

(chlortetracycline) Type A Medicated Articles

"To allow for top-dress route of administration as a Type C medicated feed for the following claim. Calves, beef and non-lactating dairy cattle. For the treatment of bacterial enteritis caused by *Escherichia coli* and for bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline."

Sponsored by :

ALPHARMA, INC.

NADA 048-761

FOIS-1

**I. GENERAL INFORMATION**

- NADA Number:** 048-761
- Sponsor:** Alpharma, Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024
- Established Name:** Chlortetracycline
- Proprietary Name:** AUREOMYCIN® 50, 90 or 100 GRANULAR
- Marketing Status:** over-the-counter
- Effects of the Supplement:** Provides for top dressing AUREOMYCIN® at the rate of 10 mg chlortetracycline (equivalent to chlortetracycline hydrochloride) per pound of bodyweight of Type C medicated feeds for cattle.

**II. INDICATIONS FOR USE**

Calves, beef and non-lactating dairy cattle. Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

**III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE**

- A. *Dosage Form:* Type A medicated article
- B. *Route of Administration:* Oral, in feed. These drugs are administered orally *ad libitum*.
- C. *Recommended Dosage:* 500 to 4000 g/ton (complete medicated cattle feed), to provide 10 mg chlortetracycline/lb bodyweight  
4000 to 20,000 g/ton (top-dress), to provide 10 mg chlortetracycline/lb bodyweight

Feed for not more than 5 days.

**IV. EFFECTIVENESS****A. Effectiveness of Dose**

The Drug Efficacy Study Implementation (DESI) of the National Academy of Science and National Research Council (NAS/NRC) provided for use of chlortetracycline at the dose described above (FR 61, 35949 - 35958, July 9, 1996).

### Pharmacokinetic Study - RVI Study No. CD-98-09

1. *Objective:* To determine whether chlortetracycline (CTC) when fed as a top-dress to growing calves is bioequivalent to CTC when mixed in the complete ration of growing calves.
2. *Investigator:* Ross W. Miller, D.V.M.  
Roche Vitamins Animal Health Research Station  
Wrightstown, New Jersey 08562-9801
3. *Design and Methods:* Twenty-four calves were divided into 2 groups of 12 in a two-treatment, two-period, two-sequence crossover design. One group of calves was dosed with 10 mg chlortetracycline per pound bodyweight mixed into a high roughage diet and the other group was dosed with 10 mg chlortetracycline per pound bodyweight top-dressed on the same diet.
4. *Test Article Administration:* Chlortetracycline was administered by providing the same medicated supplement to both treatment groups for five consecutive daily feedings. Twenty-three days of non-medicated feed were provided between dosing periods of the study.
5. *Sampling:* Blood samples were collected immediately prior to the fifth daily dose and at 3, 6, 9, 12, 18, 24, 30, 36, 48, 60, 72, 84, 96, and 108 hours after cattle received the fifth daily dose of chlortetracycline. Serum was analyzed by microbiological methods for activity of chlortetracycline.
6. *Results:* The bioequivalence of chlortetracycline when administered as either a top-dress formulation or as a complete feed was confirmed on the basis of peak drug concentrations ( $C_{max}$ ) and the extent of systemic exposure (area under the curve, AUC). Since chlortetracycline is associated with a terminal elimination half-life of approximately 15 hours, five sequential days of dosing results in near steady state conditions (where 5 multiples of  $t_{1/2}$  results in approximately 97% steady state concentrations). This point was illustrated by the similar predose (hrs zero) values seen on days 4 and 5 and hr 24 values after the fifth dose (Table 4.1). Therefore,  $AUC_{0-24}$  values that are estimated after dose 5 should be comparable to those  $AUC_{0-inf}$  values after a single dose.

**Table 4.1: Hr zero concentrations**

Day	Time	TRT 1	TRT 2
4	Hr 0	0.134	0.151
5	Hr 0	0.173	0.162
5	Hr 24	0.157	0.157

The *results* of the relative bioavailability study are summarized in Table 4.2.

**Table 4.2. Summary of bioequivalence study results**

	Top Dress (TRT 1)	Mixed (TRT 2)	Ratio TRT 1/TRT 2	90% Confidence interval (relative to TRT 2)
AUC <sub>0-24</sub>	4.2135	4.4133	0.95	89.7 - 115.3
C <sub>max</sub>	0.2205	0.2049	1.08	95.3 - 121.5
t <sub>max</sub> *	10.56	10.13	1.04	
λ <sub>z</sub>	0.04497 (t <sub>1/2</sub> = 15.4 hrs)	0.04325 (t <sub>1/2</sub> = 16.0 hrs)	1.04	96.7 - 111.2

\*Parametric confidence intervals not appropriate since t<sub>max</sub> is a discrete variable.

7. *Conclusion:* There was no indication that administering chlortetracycline in a top-dress fashion influenced its absorption or elimination based on levels of chlortetracycline in serum. Therefore, top-dressing is not expected to affect the therapeutic activity of chlortetracycline.

## V. ANIMAL SAFETY

1. *Objective:* Study No. FD32:1301 was conducted to obtain safety information on AUREOMYCIN® (chlortetracycline) when administered to cattle in their feed at a rate of 10, 20, or 30 mg chlortetracycline per pound bodyweight.
2. *Investigator:* H. Berger, and J.H. Colavita  
American Cyanamid Company, Building 301, Agriculture  
Research Division, Princeton, New Jersey
3. *Methods:* Sixteen beef steers were allotted by weight to four treatment groups, each receiving one of four experimental rations providing either 0, 10, 20, or 30 mg chlortetracycline per pound bodyweight per day. Rations were fed for 42 days. Bodyweights and pen feed consumption were determined during the experimental period and periodic blood samples were collected for various blood chemistry and hematology measurements. Steers were observed daily for symptoms of toxicity.
4. *Results:* No differences were detected in gross feed intake, weight gain, or hematological characteristics during the study. However, some statistically significant (P<0.05) differences were noted between the control and the treated groups for albumin, total bilirubin and SGOT. These differences in serum chemistry attributes were not directly related to dose of chlortetracycline or duration or exposure to the various dose rates. Although statistical differences were detected for these characteristics, all mean values were within accepted normal ranges for each respective characteristic and were judged to be of no biological significance.
5. *Conclusion:* There was no indication that administering chlortetracycline in a dose up to 30 mg per pound bodyweight had any deleterious affect on cattle physiology. Therefore, in cases where cattle of mixed health compete for feed,

i.e., where potentially variable feed intake exists between cattle within a pen, over-consumption of the 10 mg per pound bodyweight dose rate would not be expected to adversely impact health.

## VI. HUMAN SAFETY

- A. *Toxicity Studies:* Safety of the approved product, chlortetracycline premix, has been established by data in the original application, NADA 48-761.
- B. *Tolerance and Acceptable Daily Intake:* Tolerances for chlortetracycline in edible tissue of beef and non-lactating dairy cattle are established as 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
- C. *Residue Study Confirming the Withdrawal Time:*
- Objective:* This study (RVI Study No. CD-98-04) was conducted to determine if feeding chlortetracycline to cattle at the rate of 10 mg per pound bodyweight as a top-dress is likely to cause a residue of chlortetracycline, at zero withdrawal, that is greater than the published tolerance.
  - Investigator:* Ross W. Miller, D.V.M.  
Roche Vitamins Animal Health Research Station  
Wrightstown, New Jersey 08562-9801
  - Design and Methods:* Ten calves were divided into 2 groups. The control group (2 steers and 2 heifers) received a diet without chlortetracycline and served to verify that methods were suitable for detection of tissue residues. The treated group (3 steers and 3 heifers) was dosed with 1 mg lasalocid per 2.2 pounds bodyweight and 10 mg chlortetracycline per pound bodyweight for 14 days. Lasalocid was included to provide residue data on the combination use of the drugs for another application. Chlortetracycline was dosed by top-dressing a medicated supplement on the diet after the complete ration was delivered to the feed bunk. Kidneys and livers were collected from both treatment groups within 12 hours after consumption of their respective diets on the 14<sup>th</sup> day of feeding. The concentration of chlortetracycline in kidney was determined by the approved microbiological method. The concentration of lasalocid in liver was determined by an established HPLC method.
  - Results:*

Mean Residues of Lasalocid in Liver and Chlortetracycline in Kidney Collected from Cattle Treated with Feed Containing 1 mg lasalocid per 2.2 pounds bodyweight (mixed into diet) and 10 mg chlortetracycline per pound bodyweight (provided as a top dressing) for 14 days.		
Withdrawal Time in Hours	Lasalocid (ppm)	Chlortetracycline (ppm)
0	0.042 ± 0.025	1.730 ± 0.965

Samples of control kidney were fortified with lasalocid and control liver were fortified with chlortetracycline. The data showed that the presence of lasalocid did not interfere with the assay of chlortetracycline and the presence of chlortetracycline did not interfere with the assay of lasalocid.

Residues of lasalocid and chlortetracycline were below their respective tolerances at zero withdrawal, the established withdrawal period for each of the drugs, thereby indicating an absence of interference.

- D. *Regulatory Method:* The regulatory method for detection of chlortetracycline residues is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778) as the test organism (Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols, Food and Drug Administration, Washington, D.C., 1968.) This method is on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

## VII. AGENCY CONCLUSIONS

The information submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 CFR Part 514 of the implementing regulations. The data demonstrate that top-dressing and mixing chlortetracycline in complete feed provide the same therapeutic effect and that no deleterious effects occur in cattle consuming up to 30 mg chlortetracycline per pound bodyweight.

The data demonstrate that residues of chlortetracycline provided as a top-dressing were below the tolerance at zero withdrawal.

There is reasonable certainty that the conditions of use, including directions on labeling, can and will be followed in practice. The agency has concluded that this product shall retain over-the-counter marketing status.

In accordance with 21 CFR 514.106 (b)(2)(iv), this is a category II change which did not require reevaluation of the safety or effectiveness data in the parent application.

The Agency has carefully considered the potential environmental effects of this action and has concluded that the action qualifies for a categorical exclusion from the requirement of preparing an environmental assessment in accordance with 21 CFR 25.33(a)(1).

Under Section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals qualifies for 3 years of marketing exclusivity, because the application contains substantial evidence of the effectiveness of the drug involved, studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored

by the applicant. The three years of marketing exclusivity applies only to the claim for administration of chlortetracycline to cattle as a top-dress on feed for the treatment of enteritis and pneumonia.

### VIII. APPROVED PRODUCT LABELING

- A. Facsimile label - AUREOMYCIN® 50 GRANULAR Type A Medicated Article
- B. Facsimile label - AUREOMYCIN® 90 GRANULAR Type A Medicated Article
- C. Facsimile label - AUREOMYCIN® 100 GRANULAR Type A Medicated Article
- D. Blue Bird CTC Top-Dress Type C Cattle Feed Medicated
- E. Blue Bird CTC Type C Cattle Feed Medicate

Applicable labels may be obtained by writing to the following:

Freedom of Information Staff (HFI-35)  
Food and Drug Administration, Room 12A16  
5600 Fishers Lane  
Rockville, Maryland 20857

**BLUE BIRD CTC  
TYPE C Cattle Feed  
Medicated**

Calves, beef, and non-lactating dairy cattle. For treatment of bacterial enteritis caused by *E. coli* and for bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.

**Active Drug Ingredient**

Chlortetracycline (as chlortetracycline hydrochloride equivalent) ..... 500 to 4000 g/ton\*

**Guaranteed Analysis**

Crude protein, not less than .....	_____	%
Crude fat, not less than .....	_____	%
Crude fiber, not more than .....	_____	%
Calcium, not less than .....	_____	%
Calcium, not more than .....	_____	%
Phosphorus, not less than .....	_____	%
Potassium, not less than .....	_____	%
Salt <sup>1</sup> , not less than .....	_____	%
Salt <sup>1</sup> , not more than .....	_____	%
Sodium <sup>2</sup> , not less than .....	_____	%
Sodium <sup>2</sup> , not more than .....	_____	%

<sup>1</sup>If added.

<sup>2</sup>Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

**Ingredients**

Ingredients as defined by AAFCO

**Feeding Directions**

Feed continuously for not more than 5 days, providing chlortetracycline at a rate of 10 mg per pound of body weight daily. \_\_\_\_\* pounds of this cattle feed will medicate 100 lbs of body weight.

**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.

**NET WEIGHT ON BAG OR BULK**

Blue Bird Feed Mill  
Robin, IN 12345

\* Label must show actual concentration of chlortetracycline, which will vary with body weight and feed consumption to provide 10 mg/lb body weight per day. The following table provides examples of feeding rates and amount of drug in feed.

Drug Level in Feed		Lbs of Cattle Feed per 100 lbs Body Weight
mg/lb	grams/ton	
250	500	4.0
286	571	3.5
333	667	3.0
500	1000	2.0
1000	2000	1.0
2000	4000	0.5

**BLUE BIRD CTC Top Dress  
TYPE C Cattle Feed  
Medicated**

Calves, beef, and non-lactating dairy cattle. For treatment of bacterial enteritis caused by *E. coli* and for bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.

**Active Drug Ingredient**

Chlortetracycline (as chlortetracycline hydrochloride equivalent) ..... 4,000 to 20,000 g/ton\*

**Guaranteed Analysis**

Crude protein, not less than .....	_____	%
Crude fat, not less than .....	_____	%
Crude fiber, not more than .....	_____	%
Calcium, not less than .....	_____	%
Calcium, not more than .....	_____	%
Phosphorus, not less than .....	_____	%
Potassium, not less than .....	_____	%
Salt <sup>1</sup> , not less than .....	_____	%
Salt <sup>1</sup> , not more than .....	_____	%
Sodium <sup>2</sup> , not less than .....	_____	%
Sodium <sup>2</sup> , not more than .....	_____	%

<sup>1</sup>If added.

<sup>2</sup>Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

**Ingredients**

Ingredients as defined by AAFCO

**Feeding Directions**

Administer as a top dress supplement on the daily ration for not more than 5 days, providing chlortetracycline at a rate of 10 mg per pound of body weight daily. \_\_\_\_\* pounds of this top dress supplement will medicate 100 lbs of body weight.

**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.

**NET WEIGHT ON BAG OR BULK**

Blue Bird Feed Mill  
Robin, IN 12345

\* Label must show actual concentration of chlortetracycline, which will vary with body weight and feed consumption to provide 10 mg/lb body weight per day. The following table provides examples of feeding rates and amount of drug in feed.

Drug Level in Feed		Lbs of Top Dress Supplement per 100 lbs Body Weight
mg/lb	grams/ton	
2000	4000	0.5
4000	8000	0.25
5000	10000	0.2
7500	15000	0.15
10000	20000	0.1







**Active drug ingredient** Chlortetracycline calcium complex equivalent to 90 g chlortetracycline HCl/b.

**Ingredients** Dried *Streptomyces aureofaciens* Fermentation Product and Calcium Sulfate.

**For use in the manufacture of medicated animal feeds**

**Use directions** Mix sufficient Aureomycin 90 Granular Medicated Article to supply desired concentration of chlortetracycline per ton with part of the feed ingredients to make a preblend. Add the remainder of the ingredients and mix thoroughly. For specific use levels, see **Indications**.

Mixing directions	Level desired, g/ton	Amount of medicated article per ton <sup>†</sup>	† It is recommended that 1 pound 2 ounces of Aureomycin 90 Granular Type A Medicated Article be diluted with 2 pounds 14 ounces of one of the feed ingredients to form a 4 pound working premix. Use 2 pounds of the working premix to make a preblend (see Use directions) for a Type C feed containing 50 g Aureomycin chlortetracycline / ton of feed.
	50	9 oz	
	100	1 lb 2 oz	
	200	2 lb 4 oz	
	400	4 lb 8 oz	
	500	5 lb 9 oz	

Indications	Chlortetracycline mg / lb body wt / day	Indications	In complete feed Chlortetracycline g / ton
<b>Cattle</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Calves (up to 250 lb): Increased rate of weight gain and improved feed efficiency.  Beef Cattle (over 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.  Beef and Non-Lactating Dairy Cattle (over 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline when delivered in a free-choice feed. Free-choice feed must be manufactured under a feed mill license utilizing an FDA approved formulation.  Calves, Beef and Non-Lactating Dairy Cattle: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline. Feed for not more than 5 days. The appropriate amount of Aureomycin-containing feed supplement may be mixed in the cattle's daily ration or administered as a top-dress. If the Aureomycin-containing feed supplement is administered as a top-dress, it must be spread uniformly on top of the ration and sufficient space must be provided so that all cattle can eat at the same time.	0.1	<b>Swine</b> Increased rate of weight gain and improved feed efficiency.  Reduction in the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E <i>Streptococci</i> susceptible to chlortetracycline.  Breeding Swine: Control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline. Feed continuously for not more than 14 days.  <b>Sheep</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Increased rate of weight gain and improved feed efficiency.  <b>Ducks</b> Control and treatment of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. Feed in complete ration to provide from 8 to 28 mg per pound of body weight per day depending upon age and severity of disease. Feed for not more than 21 days.  <b>Chickens</b> Increased rate of weight gain and improved feed efficiency.  Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.  Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.  Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.	10-50 50-100 400
	0.5		200-400
	0.5 to 2.0		10-50
	10		100-200
	10		200-400
<b>Swine</b> Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. Feed for not more than 14 days.	10	<b>Turkeys</b> Increased rate of weight gain and improved feed efficiency.  Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	10-50 200
<b>Turkeys</b> Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	25	<b>Turkeys</b> Control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.  Turkey Poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.	400 400
<b>Indications</b>	mg / head / day	<b>Indications</b>	mg/g feed
<b>Cattle</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Calves (250 to 400 lb): Increased rate of weight gain and improved feed efficiency.  Growing Cattle (over 400 lb): Increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.  Beef Cattle: Control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.  Beef Cattle (under 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.	25-70	<b>Psittacine birds</b> <b>Warning:</b> 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. <b>Caution:</b> Aspergilliosis may occur following prolonged treatment.  Treatment of psittacine birds (parrots, macaws, cockatoos) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline. Feed continuously for 45 days. Each bird should consume an amount of medicated feed equal to one-fifth of its body weight daily. During treatment, parrots, macaws, and cockatoos should be kept individually or in pairs in clean cages.	
	70		
	350		
	350		
<b>Sheep</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Breeding Sheep: Reduction in the incidence of (vibriotic) abortions caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.	80		10

**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. Not to be fed to ducks or turkeys producing eggs for human consumption.

NADA 48-761, Approved by FDA

Marketed by  
  
 Animal Health Division  
 Alpharma Inc.  
 One Executive Drive  
 Fort Lee, New Jersey 07024

Take Time  
  
 Observe Label Directions

Net wt 50 LB (22.68 kg)



**Active drug ingredient** Chlortetracycline calcium complex equivalent to 100 g chlortetracycline HCl/lb.

**Ingredients** Dried *Streptomyces aureofaciens* Fermentation Product and Calcium Sulfate.

**For use in the manufacture of medicated animal feeds**

**Use directions** Mix sufficient Aureomycin 100 Granular Medicated Article to supply desired concentration of chlortetracycline per ton with part of the feed ingredients to make a preblend. Add the remainder of the ingredients and mix thoroughly. For specific use levels, see **Indications**.

Mixing directions	Level desired, g/ton	Amount of medicated article per ton <sup>†</sup>	† It is recommended that 1 pound of Aureomycin 100 Granular Type A Medicated Article be diluted with 3 pounds of one of the feed ingredients to form a 4 pound working premix. Use 2 pounds of the working premix to make a preblend (see Use directions) for a Type C feed containing 50 g Aureomycin chlortetracycline / ton of feed.
	50	½ lb	
	100	1 lb	
	200	2 lb	
	400	4 lb	
	500	5 lb	

Indications	Chlortetracycline mg / lb body wt / day	Indications	In complete feed Chlortetracycline g / ton
<b>Cattle</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Calves (up to 250 lb): increased rate of weight gain and improved feed efficiency.  Beef Cattle (over 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.  Beef and Non-Lactating Dairy Cattle (over 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline when delivered in a free-choice feed. Free-choice feed must be manufactured under a feed mill license utilizing an FDA approved formulation.  Calves, Beef and Non-Lactating Dairy Cattle: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline. Feed for not more than 5 days. The appropriate amount of Aureomycin-containing feed supplement may be mixed in the cattle's daily ration or administered as a top-dress. If the Aureomycin-containing feed supplement is administered as a top-dress, it must be spread uniformly on top of the ration and sufficient space must be provided so that all cattle can eat at the same time.	0.1	<b>Swine</b> Increased rate of weight gain and improved feed efficiency.  Reduction in the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E <i>Streptococci</i> susceptible to chlortetracycline.  Breeding Swine: Control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline. Feed continuously for not more than 14 days.	10-50 50-100 400
	0.5	<b>Sheep</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Increased rate of weight gain and improved feed efficiency.	20-50
	0.5 to 2.0	<b>Ducks</b> Control and treatment of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. Feed in complete ration to provide from 8 to 28 mg per pound of body weight per day depending upon age and severity of disease. Feed for not more than 21 days.	200-400
	10	<b>Chickens</b> Increased rate of weight gain and improved feed efficiency.  Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.  Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.  Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.	10-50 100-200 200-400 500
	10	<b>Turkeys</b> Increased rate of weight gain and improved feed efficiency.  Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	10-50 200
25	<b>Turkeys</b> Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronavirus enteritis) susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	<b>Indications</b> Control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.  Turkey Poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.	400 400

Indications	mg / head / day	Indications	mg/g feed
<b>Cattle</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Calves (250 to 400 lb): increased rate of weight gain and improved feed efficiency.  Growing Cattle (over 400 lb): increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.  Beef Cattle: Control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.  Beef Cattle (under 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.	25-70	<b>Psittacine birds</b> <b>Warning:</b> 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. <b>Caution:</b> Aspergilliosis may occur following prolonged treatment.  Treatment of psittacine birds (parrots, macaws, cockatoos) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline. Feed continuously for 45 days. Each bird should consume an amount of medicated feed equal to one-fifth of its body weight daily. During treatment, parrots, macaws, and cockatoos should be kept individually or in pairs in clean cages.	10
	70		
	350		
350			
<b>Sheep</b> <b>Caution:</b> For use in dry feed only. Not for use in liquid type B medicated feeds.  Breeding Sheep: Reduction in the incidence of (vibriotic) abortions caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.	80		

**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. Not to be fed to ducks or turkeys producing eggs for human consumption.

NADA 48-761, Approved by FDA

Marketed by



Animal Health Division

Alpha Pharma Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024

Take Time  
Observe Label Directions



Net wt 50 LB (22.68 kg)