

HFA-305

Date of Approval Letter:

NOV 15 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 48-761

**Aureomycin[®] 50 Granular, Aureomycin[®] 90 Granular, and
Aureomycin[®] 100 Granular (chlortetracycline)
Type A Medicated Articles**

"control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline"

Sponsored by:
Alpharma Inc.

48-761 - FOIS 1

I. GENERAL INFORMATION

NADA Number: 48-761

Sponsor: Alpharma Inc.
One Executive Drive
Fort Lee, New Jersey 07024

Established Name: chlortetracycline

Proprietary Names: Aureomycin[®] 50 Granular, Aureomycin[®] 90 Granular, and Aureomycin[®] 100 Granular (chlortetracycline) Type A Medicated Articles

Marketing Status: Over-the-counter (OTC)

Effect of Supplement: This supplemental application adds the claim for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

II. INDICATIONS FOR USE

Swine: ✓ Control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. ✓

Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

Increased rate of weight gain and improved feed efficiency.

Reduction in the incidence of cervical lymphadenitis (jowl abscess) caused by Group E *Streptococci* susceptible to chlortetracycline.

Breeding Swine: Control of leptospirosis (reducing the incidence of abortion and shedding of *leptospirae*) caused by *Leptospira pomona*.

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

JUL 11 1971
DOSAGE

A. Dosage Form: Type A Medicated Article

B. Route of Administration: Oral, in feed

C. Recommended Dosage: In Type C medicated feed, chlortetracycline to deliver a daily dose of 10 mg/lb body weight (approximately 400 grams per ton) for not more than 14 days.

IV. EFFECTIVENESS

The claim for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline in swine treated with 10 mg chlortetracycline per lb body weight for up to 14 days in feed was approved on July 7, 2000, for Alpharma's ChlorMax™ (65 FR 42881, July 26, 2000).

ChlorMax™ (chlortetracycline, NADA 46-699) and Aureomycin® NADA 48-761 were both found to comply with the results of NAS/NRC and DESI evaluation for effectiveness as published in the Federal Register (61 FR 35949-35958, July 9, 1996). These products approved under the DESI process were found to be equivalent at the codified levels for swine and other species.

Aureomycin® and ChlorMax™ were shown equivalent under DESI evaluation. Alpharma Inc. owns both products. As such, Alpharma Inc. may reference data found in NADA 46-699. Aureomycin® and ChlorMax™ now have identical indications. For the purposes of this supplement, no new studies were conducted to establish effectiveness associated with the use of chlortetracycline in swine.

V. ANIMAL SAFETY

The target animal information is contained in the FOI Summary for the original approval of NADA 48-761. No new data were generated for this supplement because the dosage of CTC for this indication remains within the approved dose range for swine.

VI. HUMAN SAFETY

The current tolerance established for the sum of residues of the tetracyclines, including chlortetracycline, in tissues of swine is 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney, as described in 21 CFR 556.150. Chlortetracycline has a zero-day pre-slaughter withdrawal period in swine, as described in 21 CFR 558.128.

VII. AGENCY CONCLUSIONS

The information submitted in support of this NADA and in the referenced files satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The information demonstrates that Aureomycin[®] Type A Medicated Article when administered in swine feed is safe and effective when used as described in Section II and III .

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did not require a 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 is categorically excluded under 21 CFR 25.33(a)(1) from the requirement to prepare an environmental assessment (EA).

Under Section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity because the application contains no new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant.

There are currently no U.S. patents Aureomycin[®] Type A Medicated Article.

VII. APPROVED PRODUCT LABELING

Copies of facsimile Type A Medicated Article labeling and specimen (Blue Bird) Type B and Type C medicated feed labels are attached to this document.

- A. Aureomycin[®] 50 Granular
- B. Aureomycin[®] 90 Granular
- C. Aureomycin[®] 100 Granular
- D. Blue Bird CTC 40 Type B Swine Feed Medicated
- E. Blue Bird CTC Type C Swine Feed Medicated

Copies of 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

Lot No. _____

**BLUE BIRD CTC
TYPE C SWINE FEED
MEDICATED**

For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline, and for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

ACTIVE DRUG INGREDIENTS*

Chlortetracycline (as hydrochloride) _____ g/ton**

GUARANTEED ANALYSIS

Crude Protein, not less than	_____ %
Lysine, 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	_____ %
Salt ¹ , not less than	_____ %
Salt ¹ , not more than	_____ %
Total Sodium ² , not less than	_____ %
Total Sodium ² , not more than	_____ %
Selenium, not less than	_____ ppm
Zinc, not less than	_____ ppm

¹If added.

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

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

FEEDING DIRECTIONS

Feed for not more than 14 days.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

*Final printed label on formulated Type C medicated feed must bear single concentration.

** Approximately 400 g/t; Concentration (grams per ton) must be such that feed delivers 10 mg/lb body weight daily, based on body weight and feed consumption of animals.

Lot No. _____

**BLUE BIRD CTC40
TYPE B SWINE FEED
MEDICATED**

For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

ACTIVE DRUG INGREDIENTS

Chlortetracycline (as hydrochloride)..... 40 g/lb

GUARANTEED ANALYSIS

Crude Protein, not less than %
Lysine, 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 %
Salt¹, not less than %
Salt¹, not more than %
Total Sodium², not less than %
Total Sodium², not more than %
Selenium, not less than ppm
Zinc, not less than ppm

¹If added.

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

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

MIXING DIRECTIONS

Mix 10 pounds of this Type B medicated feed with non-medicated feed ingredients to manufacture one ton of complete (Type C) medicated swine feed containing 400 grams³ of chlortetracycline. This Type C medicated feed should be fed to swine for not more than 14 days.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

³ equivalent to 10 mg/lb body weight daily

Lot No. _____

**BLUE BIRD CTC40
TYPE B SWINE FEED
MEDICATED**

For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

ACTIVE DRUG INGREDIENTS

Chlortetracycline (as hydrochloride).....40 g/lb

GUARANTEED ANALYSIS

Crude Protein, not less than	_____ %
Lysine, 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	_____ %
Salt ¹ , not less than	_____ %
Salt ¹ , not more than	_____ %
Total Sodium ² , not less than	_____ %
Total Sodium ² , not more than	_____ %
Selenium, not less than	_____ ppm
Zinc, not less than	_____ ppm

¹If added.

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

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

MIXING DIRECTIONS

Mix 10 pounds of this Type B medicated feed with non-medicated feed ingredients to manufacture one ton of complete (Type C) medicated swine feed containing 400 grams³ of chlortetracycline. This Type C medicated feed should be fed to swine for not more than 14 days.

NET WEIGHT ON BAG OR BULK

Blue Bird Feed Mill
Robin, IN 12345

³ equivalent to 10 mg/lb body weight daily

Aureomycin

50 Granular

Chlortetracycline

Type A Medicated Article

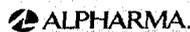
Active drug ingredient	Chlortetracycline calcium complex equivalent to 50 g chlortetracycline hydrochloride per lb.																
Ingredients	Dried <i>Streptomyces aureofaciens</i> Fermentation Product and Calcium Sulfate																
For use in the manufacture of medicated animal feeds.																	
For use in dry feed only. Not for use in liquid type B medicated feeds.																	
Use directions:	Mix sufficient Aureomycin 50 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	<table border="1"> <thead> <tr> <th>Level desired grams per ton</th> <th>Amount of medicated article per ton¹</th> </tr> </thead> <tbody> <tr><td>10</td><td>1/5 lb</td></tr> <tr><td>50</td><td>1 lb</td></tr> <tr><td>100</td><td>2 lb</td></tr> <tr><td>200</td><td>4 lb</td></tr> <tr><td>400</td><td>8 lb</td></tr> <tr><td>500</td><td>10 lb</td></tr> </tbody> </table>	Level desired grams per ton	Amount of medicated article per ton ¹	10	1/5 lb	50	1 lb	100	2 lb	200	4 lb	400	8 lb	500	10 lb	¹ It is recommended that 1 pound of Aureomycin 50 Granular Type A Medicated Article be diluted with 4 pounds of one of the feed ingredients to form a 5 pound working premix. Use 1 pound of the working premix to make a preblend (see Use Directions) for a Type C ² feed containing 10 g Aureomycin chlortetracycline / ton of feed.	
Level desired grams per ton	Amount of medicated article per ton ¹																
10	1/5 lb																
50	1 lb																
100	2 lb																
200	4 lb																
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Indications	Chlortetracycline mg per lb body wt per day	Indications	In complete feed Chlortetracycline g per ton														
Cattle 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.	0.1 0.5 0.5-2.0 10	Swine Increased rate of weight gain and improved feed efficiency. Reduction in the incidence of cervical lymphadenitis (owl 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 zomona</i> susceptible to chlortetracycline. Feed continuously for not more than 14 days. Sheep Increased rate of weight gain and improved feed efficiency. Ducks 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.	10-50 50-100 400 20-50 200-400														
Swine Control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline. 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. (Note: this dose is equivalent to 400 grams per ton, depending on feed consumption and body weight). Feed for not more than 14 days.	10	Chickens 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.	10-50 100-200 200-400														
Turkeys Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	25	Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days. Turkeys Increased rate of weight gain and improved feed efficiency.	500 10-50														
Indications	mg per head per day	Indications	mg per g feed														
Cattle 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 spp.</i> 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 70 350 350	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days. 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.	200 400 400														
Sheep Breeding Sheep: Reduction in the incidence of (vibronic) abortions caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.	80	Psittacine birds 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. Caution: Aspergillosis 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														

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)

700334 0108

ALPHARMA

Aureomycin[®]

90 Granular

Aureomycin[®]
90 Granular

Aureomycin[®]
90 Granular



Chlortetracycline
Type A Medicated Article

Net wt 50 LB (22.68 kg)

ALPHARMA

Aureomycin is a registered trademark of Alpharma Inc.

Aureomycin[®]

90 Granular

Chlortetracycline

Type A Medicated Article

Active drug ingredients: Chlortetracycline calcium complex equivalent to 50 g chlortetracycline hydrochloride per lb.

Ingredients: Great Lakes Veterinary Antimicrobial Formulation Product and Calcium Sulfate

For use in the manufacture of medicated animal feeds.
For use in dry feed only. Not for use in liquid type B medicated feeds.

Use directions: Mix with 1 lb. Aureomycin 90 Granular Medicated Article to supply desired concentration of chlortetracycline per unit part of the feed ingredients to make a product. Add the remainder of the ingredients and mix thoroughly. For specific use levels, see Indications.

Mixing directions	Level desired (grams per ton)	Aureomycin 90 Granular (pounds per ton)	1 lb. is approximately equal to 2.205 pounds of chlortetracycline 90 Granular. Add a level and add the remainder of the ingredients and mix thoroughly. For specific use levels, see Indications.
	50	2.205	
	100	4.410	
	200	8.820	
	400	17.640	
	500	22.050	

Indications	Use Level (grams per ton)	Use Level (pounds per ton)
Cattle Control up to 22.8% increased rate of weight gain and improved feed efficiency. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract.	500	22.050
Swine Increased rate of weight gain and improved feed efficiency. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract.	500	22.050
Sheep Increased rate of weight gain and improved feed efficiency. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract.	500	22.050
Chickens Increased rate of weight gain and improved feed efficiency. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract.	500	22.050
Turkeys Increased rate of weight gain and improved feed efficiency. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract.	500	22.050
Poultry Birds Increased rate of weight gain and improved feed efficiency. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract. Best Control: 1000 mg. Control of other infections of the respiratory tract and of the digestive tract.	500	22.050

Warning: A withdrawal period has not been established for the product for use in breeding animals. Do not use in breeding animals. Do not use in breeding animals.

ALPHARMA, Inc. Approved by FDA.

ALPHARMA
Aureomycin 90 Granular
Net wt 50 LB (22.68 kg)

Take Care
Chlortetracycline
Type A Medicated Article

100915 0108

Aureomycin[®]

90 Granular Chlortetracycline Type A Medicated Article

Active drug ingredient	Chlortetracycline calcium complex equivalent to 90 g chlortetracycline hydrochloride per lb.
Ingredients	Dried <i>Streptomyces aureofaciens</i> Fermentation Product and Calcium Sulfate.

For use in the manufacture of medicated animal feeds.
For use in dry feed only. Not for use in liquid type B medicated 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 grams per ton	Amount of medicated article per ton[†]	† 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 per lb body wt per day	Indications	In complete feed Chlortetracycline g per ton
Cattle 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.	0.1 0.5 0.5-2.0 10	Swine 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. Sheep Increased rate of weight gain and improved feed efficiency. Ducks 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.	10-50 50-100 400 20-50 200-400
Swine Control of porcine proliferative enteropathies (leitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline. 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. (Note: this dose is equivalent to 400 grams per ton, depending on feed consumption and body weight). Feed for not more than 14 days.	10	Chickens 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
Turkeys Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	25	Turkeys 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 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.	10-50 200 400 400
Indications	mg per head per day	Indications	mg per g feed
Cattle 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 70 350 350	Psittacine birds 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. Caution: Aspergillosis 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
Sheep 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
ALPHARMA.
 Animal Health Division
 Alpha Inc.
 One Executive Drive
 Fort Lee, New Jersey 07024

Take Time

 Observe Label
 Directions

Net wt 50 LB (22.68 kg)

700335 0108

Aureomycin®

100 Granular

Chlortetracycline Type A Medicated Article

Active drug ingredient	Chlortetracycline calcium complex equivalent to 100 g chlortetracycline hydrochloride per lb.
Ingredients	Dried <i>Streptomyces aureofaciens</i> Fermentation Product and Calcium Sulfate.

For use in the manufacture of medicated animal feeds.
For use in dry feed only. Not for use in liquid type B medicated 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 grams per ton	Amount of medicated article per ton [†]	† It is recommended that 1 pound of Aureomycin 100 Granular Type A Medicated Article be diluted with 2 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	1/2 lb	
	100	1 lb	
	200	2 lb	
	400	4 lb	
	500	5 lb	

Indications	Chlortetracycline mg per lb body wt per day	Indications	In complete feed Chlortetracycline g per ton
Cattle Calves (up to 250 lb): Increased rate of weight gain and improved feed efficiency.	0.1	Swine Increased rate of weight gain and improved feed efficiency.	10-50
Beef Cattle (over 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.	0.5	Reduction in the incidence of cervical lymphadenitis (owl abscesses) caused by <i>Group E Streptococci</i> susceptible to chlortetracycline.	50-100
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.	0.5-2.0	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.	400
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.	10	Sheep Increased rate of weight gain and improved feed efficiency.	20-50
Swine Control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline. 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. (Note: this dose is equivalent to 400 grams per ton, depending on feed consumption and body weight). Feed for not more than 14 days.	10	Ducks 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
Turkeys Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronavirus enteritis) susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	25	Chickens Increased rate of weight gain and improved feed efficiency.	10-50
Indications	mg per head per day	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	100-200
Cattle Calves (250 to 400 lb): Increased rate of weight gain and improved feed efficiency.	25-70	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.	200-400
Growing Cattle (over 400 lb): Increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	70	Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.	500
Beef Cattle: Control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.	350	Turkeys Increased rate of weight gain and improved feed efficiency.	10-50
Beef Cattle (under 700 lb): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.	350	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	200
Sheep Breeding Sheep: Reduction in the incidence of (vibriotic) abortions caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.	80	Control of haxamitosis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	400
		Turkey Poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.	400
		Indications	mg per g feed
		Psittacine birds 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. Caution: Aspergillosis may occur following prolonged treatment.	10
		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.	

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 Inc.
 One Executive Drive
 Fort Lee, New Jersey 07024

Take Time



Observe Label Directions

Net wt 50 LB (22.68 kg)

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