

Date of Approval: OCT 26 1998

**FREEDOM OF INFORMATION SUMMARY**

**SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION**

NADA 48-761

Chlortetracycline (CTC)

Type A Medicated Article

Sponsored by:

Roche Vitamins, Inc.

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION

NADA Number 48-761

Sponsor: Roche Vitamins Inc.  
Parsippany, NJ 07054

Generic Name: Chlortetracycline Pre-mix

Trade Name: AUREOMYCIN Type A Medicated Article

Marketing Status: OTC

Effect of the Supplement: Changes the withdrawal time from 24 hours to zero (0) day withdrawal when chlortetracycline is fed to chickens at 500 g/ton of feed for 5 days for reduction of mortality due to Escherichia coli infections susceptible to chlortetracycline.

2. INDICATIONS FOR USE: See below

3. A. DOSAGE FORM: Type A Medicated Article

B. ROUTE OF ADMINISTRATION: Oral - For use in Type C medicated chicken feeds.

C. RECOMMENDED DOSAGES:

<u>Dosage</u>	<u>Indication for use</u>
<u>CHICKENS</u>	
10-50 g/t	Broiler/fryer chickens: For increased rate of weight gain and improved feed efficiency.
100-200 g/t	Control of infectious synovitis caused by <u>Mycoplasma synoviae</u> susceptible to chlortetracycline. (Feed continuously for 7 to 14 days )

200-400 g/t Control of chronic respiratory disease (CRD) and air sac infection caused by Mycoplasma gallisepticum and Escherichia coli susceptible to chlortetracycline.  
(Feed continuously for 7 to 14 days)

**WARNING**

**Zero-day withdrawal period.**

500 g/t Reduction of mortality due to Escherichia coli infections susceptible to chlortetracycline.  
(Feed for 5 days)

**WARNING**

**Zero-day withdrawal period.**

4. EFFECTIVENESS: No further effectiveness data were required.
5. ANIMAL SAFETY: No further safety data were required.
6. HUMAN FOOD SAFETY:

**A. Safe Concentrations of Total Residues**

Recently, the Center for Veterinary Medicine (CVM) revised the tolerances for tetracycline drugs (61 FR 67453 ). Based on that reevaluation, tolerances for total tetracycline residues in tissues are established as follows:

2 ppm in muscle  
6 ppm in liver  
12 ppm in kidney  
12 ppm in fat  
0.4 ppm in eggs

**B. Studies to Establish a Withdrawal Time**

I. Study # A-62-5-FT  
Investigator:

J. J. Drain, American Cyanamid Company,  
Princeton, NJ 08543-0400

Objective:

To study the magnitude of chlortetracycline (CTC) residues in chicken blood and tissues following high level dietary supplementation at 800, 1200, 1600, and 2000 g/ton for 5 days.

**Summary and Conclusions:** One hundred and fifty ten-week-old broilers were fed low calcium diets containing 0, 800, 1200, 1600 and 2000 gms. chlortetracycline per ton of feed. Period of medication was five days. CTC concentrations of blood and tissues were determined by microbiological assay. Five birds were utilized for each treatment at each sampling (0-day, 1-day, 3-days, 6-days, 8-days and 120 days of withdrawal). All tissues from all control birds were negative (less than 0.025 mcg CTC/gm tissue) for CTC. Only data from birds fed 800 gm CTC/ton of feed are summarized in Table below:

**Concentration (ppm) of chlortetracycline (CTC) in edible tissue of chickens following identified withdrawal period after treatment with 800 gms CTC per ton of feed for 5 days.**

RESIDUES OF CTC (PPM) IN				
DAY OF WITHDRAWAL	MUSCLE	FAT	LIVER	KIDNEY
0	0.38	0.09	0.90	6.44
1	0.01	Neg.*	0.02	0.16
3	Neg.	Neg.	0.01	0.12
6	Neg.	Neg.	Neg.	0.08
8	Neg.	Neg.	Neg.	0.07
10	Neg.	Neg.	Neg.	0.05

\*Negative indicates value of less than 0.025 mcg CTC/gm tissue

**C. Calculating the Withdrawal Time**

All of the residues in both kidney and liver are less than the assigned tolerances for all slaughter points. The calculated 99th percentile/95% confidence limit for liver residues at zero withdrawal is significantly less than the 6 ppm tolerance for liver residues.

**D. Regulatory Analytical Methods for Residues**

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Bacillus cereus* var *mycoides* (ATCC 11778). The method is found in Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols, Revised October 1968, Reprinted

December 1974, Nation Center for Antibiotic and Insulin Analysis, FDA,  
Washington, DC 20204.

7. AGENCY CONCLUSIONS:

This supplemental NADA satisfies the requirements of section 512 of the Act and demonstrates that AUREOMYCIN Type A Medicated Article when used under its proposed conditions of use, is safe and effective for the labeled indications. The supplemental approval provides for the use of this chlortetracycline premix fed to chickens at 500 g/ton of feed for 5 days for reduction of mortality due to Eschericha coli infections with a zero-day withdrawal time.

The "probably effective" finding of the NAS/NRC/DESI regarding chlortetracycline hydrochloride was published in the **FEDERAL REGISTER** of July 21, 1970, subsequently reviewed by FDA, resulting in the upgrade to "effective status" and was DESI-finalized and codified in the **FEDERAL REGISTER** on July 9, 1996.

When NADA 48-761 was reviewed under NAS/NRC/DESI program, it was an over-the-counter product and this marketing status remains unchanged. Other Chlortetracycline Type A Medicated Articles for use in food-producing animals are also currently on the market as over-the-counter products. Therefore, the Center for Veterinary Medicine has concluded that this product should retain over-the-counter marketing status.

Under the Center's supplemental approval policy [21 CFR 514.106(b)(2)(x)] this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. However, the approval did require a re-evaluation of the human food safety data in the parent application.

8. **Labeling:** See Attachment(s)

Aureomycin® 50, 90, and 100 premix bags

**AUREOMYCIN GRANULAR**  
**TYPE A MEDICATED ARTICLE**

# AUREOMYCIN® 50

chlortetracycline

## GRANULAR

### TYPE A MEDICATED ARTICLE

FOR USE IN THE MANUFACTURE OF ANIMAL FEEDS

**ACTIVE DRUG INGREDIENT:** Chlortetracycline calcium complex equivalent to 50 g chlortetracycline HCl/lb.

**INGREDIENTS:** Dried *Streptococcus aureus* cells Fermentation Product and Calcium Sulfate.

**USE DIRECTIONS:** Mix sufficient AUREOMYCIN 50 Granular Medicated Article to supply desired concentrations 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.

Level Desired, g/ton	Amount of Mix-Added Article per Ton
10	1/5 Lb. †
50	1 Lb.
100	2 Lb.
200	4 Lb.
400	8 Lb.
500	10 Lb.

† 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 preblend. Use 1 pound of the working preblend to make a preblend (see USE DIRECTIONS) for a Type C feed containing 10 g AUREOMYCIN chlortetracycline / ton of feed.

## INDICATIONS

<b>CATTLE</b>	<p><b>WARNING:</b> A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR VEAL.</p> <p><b>CAUTION:</b> FOR USE IN DRY FEED ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS.</p> <p><b>4.1 mg/Lb. body weight/day CALVES (UP TO 200 LB.):</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>6.6 mg/Lb. body weight/day BEEF CATTLE (OVER 700 LB.):</b> Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.</p> <p><b>6.6 to 2.0 mg/Lb. body weight/day BEEF AND NON-LACTATING DAIRY CATTLE (OVER 700 LB.):</b> Control of active infections 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.</p> <p><b>10 mg/Lb. body weight/day CALVES, BEEF AND NON-LACTATING DAIRY CATTLE:</b> 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.</p>	<p><b>20-70 mg/head/day CALVES (200 TO 400 LB.):</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>70 mg/head/day GROWING CATTLE (OVER 400 LB.):</b> Increased rate of weight gain and improved feed efficiency, and reduction of liver condemnation due to liver abscesses.</p> <p><b>300 mg/head/day BEEF CATTLE:</b> Control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.</p> <p><b>BEEF CATTLE (UNDER 700 LB.):</b> Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.</p>
	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>60-100 g/ton</b> Reduction in the incidence of cervical lymphadenitis (owl abscesses) caused by Group E <i>Streptococci</i> susceptible to chlortetracycline.</p>	<p><b>400 g/ton</b> <b>SWERING SWINE:</b> Control of leptospirosis (reducing the incidence of abortion and shedding of leptospires) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline. Feed continuously for not more than 14 days.</p> <p><b>10 mg/Lb. body weight/day</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.</p>
<b>SWINE</b>	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-400 g/ton</b> 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.</p> <p><b>500 g/ton</b> Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.</p>
	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p> <p><b>400 g/ton</b> Control of haemorrhage caused by <i>Haemorrhagic septicaemia</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>400 g/ton</b> <b>TURKEY POULTRY NOT OVER 4 WEEKS OF AGE:</b> Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.</p> <p><b>50 mg/Lb. body weight/day</b> Control of complicating bacterial organisms associated with bluecomb (traumatic) enteritis, coronavirus enteritis susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
<b>CHICKENS</b>	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-400 g/ton</b> 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.</p> <p><b>500 g/ton</b> Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.</p>
	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p> <p><b>400 g/ton</b> Control of haemorrhage caused by <i>Haemorrhagic septicaemia</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>400 g/ton</b> <b>TURKEY POULTRY NOT OVER 4 WEEKS OF AGE:</b> Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.</p> <p><b>50 mg/Lb. body weight/day</b> Control of complicating bacterial organisms associated with bluecomb (traumatic) enteritis, coronavirus enteritis susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
<b>TURKEYS</b>	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-400 g/ton</b> 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.</p> <p><b>500 g/ton</b> Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.</p>
	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p> <p><b>400 g/ton</b> Control of haemorrhage caused by <i>Haemorrhagic septicaemia</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>400 g/ton</b> <b>TURKEY POULTRY NOT OVER 4 WEEKS OF AGE:</b> Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.</p> <p><b>50 mg/Lb. body weight/day</b> Control of complicating bacterial organisms associated with bluecomb (traumatic) enteritis, coronavirus enteritis susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
<b>DUCKS</b>	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-400 g/ton</b> 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.</p> <p><b>500 g/ton</b> Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.</p>
	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p> <p><b>400 g/ton</b> Control of haemorrhage caused by <i>Haemorrhagic septicaemia</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>400 g/ton</b> <b>TURKEY POULTRY NOT OVER 4 WEEKS OF AGE:</b> Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.</p> <p><b>50 mg/Lb. body weight/day</b> Control of complicating bacterial organisms associated with bluecomb (traumatic) enteritis, coronavirus enteritis susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
<b>SHEEP</b>	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-400 g/ton</b> 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.</p> <p><b>500 g/ton</b> Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.</p>
	<p><b>10-60 g/ton</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>200 g/ton</b> Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p> <p><b>400 g/ton</b> Control of haemorrhage caused by <i>Haemorrhagic septicaemia</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>400 g/ton</b> <b>TURKEY POULTRY NOT OVER 4 WEEKS OF AGE:</b> Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.</p> <p><b>50 mg/Lb. body weight/day</b> Control of complicating bacterial organisms associated with bluecomb (traumatic) enteritis, coronavirus enteritis susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
<b>PSTACINE BIRDS</b>	<p><b>10 mg/g feed</b> Treatment of psittacosis (parrot, macaw, cockatoo) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline. Feed continuously for 45 days.</p>	<p><b>50 mg/head/day BREEDING SHEEP:</b> Reduction in the incidence of (vibronic) abortions caused by <i>Chlamydia abortus</i> infection susceptible to chlortetracycline.</p>
	<p><b>10 mg/g feed</b> Treatment of psittacosis (parrot, macaw, cockatoo) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline. Feed continuously for 45 days.</p>	<p><b>50 mg/head/day BREEDING SHEEP:</b> Reduction in the incidence of (vibronic) abortions caused by <i>Chlamydia abortus</i> infection susceptible to chlortetracycline.</p>
<p><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.</p> <p><b>CAUTION:</b> ASPERGILLIOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT.</p> <p>Parrots, Macaws, Cockatoos</p>	<p><b>WARNING:</b> NOT TO BE FED TO DUCKS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p><b>200-400 g/ton</b> Control and treatment of low cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.</p>	
<p><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.</p> <p><b>CAUTION:</b> ASPERGILLIOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT.</p> <p>Parrots, Macaws, Cockatoos</p>	<p><b>WARNING:</b> NOT TO BE FED TO DUCKS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p><b>200-400 g/ton</b> Control and treatment of low cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.</p> <p>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.</p>	
<p><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.</p> <p><b>CAUTION:</b> ASPERGILLIOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT.</p> <p>Parrots, Macaws, Cockatoos</p>	<p><b>WARNING:</b> NOT TO BE FED TO DUCKS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p><b>200-400 g/ton</b> Control and treatment of low cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.</p> <p>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.</p>	

Net Wt. 25 Lb. (2.27 kg)  
 Product Code: 500175007  
 Batch No.: See bag seal  
 Manufacture Date: See bag seal  
 ©1985 Roche



Manufactured By:  
**Roche Vitamins Inc.**  
 Parsippany, New Jersey 07054

TAKE TIME



OBSERVE LABEL DIRECTIONS

**GRANULAR**  
**TYPE A MEDICATED ARTICLE**

# AUREOMYCIN® 90

chlorotetracycline

## GRANULAR

### TYPE A MEDICATED ARTICLE

FOR USE IN THE MANUFACTURE OF ANIMAL FEEDS

**ACTIVE DRUG INGREDIENT:** Chlorotetracycline calcium complex equivalent to 90 g chlorotetracycline HCl.

**INGREDIENTS:** Dried *Streptococcus aureus* Culture Fermentation Product and Calcium Sulfate.

**USE DIRECTIONS:** Mix sufficient AUREOMYCIN 90 Granular Medicated Article to supply desired concentration of chlorotetracycline per ton with part of the feed ingredients to make a granule. Add the remainder of the ingredients and mix thoroughly.

For specific use levels, see DIRECTIONS.

Level Desired, g/ton	Amount of Medicated Article per Ton
20	0.22 <sup>1</sup>
100	1 lb. 2 oz.
200	2 lb. 4 oz.
400	4 lb. 8 oz.
800	9 lb. 8 oz.

<sup>1</sup> It is recommended that 1 part 2 ounce of AUREOMYCIN 90 Granular Type A Medicated Article be added with 2 parts 14 ounces of one of the feed ingredients to form a 4 part mixture from the 2 parts of the working granule to make a product (see USE DIRECTIONS) for a Type C feed containing 90 g AUREOMYCIN chlorotetracycline of feed.

## INDICATIONS

<b>CATTLE</b>	<p><b>WARNING:</b> A 30-DAY INDIVIDUAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN THE PREGNANT CALVES, OR NOT USE IN CALVES TO BE PRODUCED FOR VEAL.</p> <p><b>CAUTION:</b> FOR USE IN DRY FEED ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS.</p> <p><b>6.1 mg/Lb. body weight/day</b>  <b>CHICKEN (50 TO 200 LB.):</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>6.2 mg/Lb. body weight/day</b>  <b>DEEP AND NON-LACTATING DAIRY CATTLE (OVER 700 LB.):</b> Control of acute infection of endometrium caused by <i>Agaveles myxophila</i> susceptible to chlorotetracycline.</p> <p><b>6.3 to 2.0 mg/Lb. body weight/day</b>  <b>DEEP AND NON-LACTATING DAIRY CATTLE (OVER 700 LB.):</b> Control of acute infection of endometrium caused by <i>Agaveles myxophila</i> susceptible to chlorotetracycline when administered in a free-choice feed. Free-choice feed must be manufactured under a feed mill license complying with FDA approved formulae.</p> <p><b>10 mg/Lb. body weight/day</b>  <b>CATTLE, DEEP AND NON-LACTATING DAIRY CATTLE:</b> Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. Feed for not more than 5 days.</p>	<p><b>20-70 mg/ton/day</b>  <b>CHICKEN (50 TO 200 LB.):</b> Increased rate of weight gain and improved feed efficiency.</p> <p><b>70 mg/ton/day</b>  <b>DEEP AND NON-LACTATING DAIRY CATTLE (OVER 700 LB.):</b> Increased rate of weight gain and improved feed efficiency, and reduction of their endometrial due to their infection.</p> <p><b>200 mg/ton/day</b>  <b>DEEP CATTLE:</b> Control of bacterial pneumonia associated with shipping fever syndrome caused by <i>Pasteurella</i> spp. susceptible to chlorotetracycline.</p> <p><b>DEEP CATTLE (OVER 400 LB.):</b> Control of acute infection of endometrium caused by <i>Agaveles myxophila</i> susceptible to chlorotetracycline.</p>
	<p><b>10-20 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p> <p><b>20-100 g/ton</b>            Reduction in the incidence of cervical lymphadenitis (anal abscesses) caused by <i>Staph. E. Agaveles</i> susceptible to chlorotetracycline.</p>	<p><b>400 g/ton</b>  <b>SPREADING DISEASE:</b> Control of leptospirosis (reducing the incidence of abortion and shedding of leptospires) caused by <i>L. pomona</i> group susceptible to chlorotetracycline. Feed continuously for not more than 14 days.</p> <p><b>10 mg/Lb. body weight/day</b>            Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. Feed for not more than 14 days.</p>
<b>SWINE</b>	<p><b>10-20 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b>            Control of infectious myelitis caused by <i>Mycobacterium avium</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-250 g/ton</b>            Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p> <p><b>500 g/ton</b>            Reduction of mortality due to <i>Escherichia coli</i> infection susceptible to chlorotetracycline. Feed for 5 days.</p>
	<p><b>10-20 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b>            Control of infectious myelitis caused by <i>Mycobacterium avium</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-250 g/ton</b>            Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p> <p><b>500 g/ton</b>            Reduction of mortality due to <i>Escherichia coli</i> infection susceptible to chlorotetracycline. Feed for 5 days.</p>
<b>CHICKENS</b>	<p><b>10-20 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b>            Control of infectious myelitis caused by <i>Mycobacterium avium</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-250 g/ton</b>            Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p> <p><b>500 g/ton</b>            Reduction of mortality due to <i>Escherichia coli</i> infection susceptible to chlorotetracycline. Feed for 5 days.</p>
	<p><b>10-20 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p> <p><b>100-200 g/ton</b>            Control of infectious myelitis caused by <i>Mycobacterium avium</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>200-250 g/ton</b>            Control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p> <p><b>500 g/ton</b>            Reduction of mortality due to <i>Escherichia coli</i> infection susceptible to chlorotetracycline. Feed for 5 days.</p>
<b>TURKEYS</b>	<p><b>WARNING:</b> NOT TO BE FED TO TURKEYS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p><b>10-20 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p> <p><b>200 g/ton</b>            Control of infectious myelitis caused by <i>Mycobacterium avium</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p> <p><b>400 g/ton</b>            Control of bacterial enteritis caused by <i>Escherichia coli</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>400 g/ton</b>  <b>TURKEYS FEED TO NOT OVER 4 WEEKS OF AGE:</b> Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlorotetracycline.</p> <p><b>25 mg/Lb. body weight/day</b>            Control of competing bacterial organisms associated with bacterial enteritis (susceptible to chlorotetracycline) susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>
	<p><b>10-20 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p> <p><b>200 g/ton</b>            Control of infectious myelitis caused by <i>Mycobacterium avium</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p> <p><b>400 g/ton</b>            Control of bacterial enteritis caused by <i>Escherichia coli</i> susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>	<p><b>400 g/ton</b>  <b>TURKEYS FEED TO NOT OVER 4 WEEKS OF AGE:</b> Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlorotetracycline.</p> <p><b>25 mg/Lb. body weight/day</b>            Control of competing bacterial organisms associated with bacterial enteritis (susceptible to chlorotetracycline) susceptible to chlorotetracycline. Feed continuously for 7 to 14 days.</p>
<b>DUCKS</b>	<p><b>WARNING:</b> NOT TO BE FED TO DUCKS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p><b>200-400 g/ton</b>            Control and treatment of viral enteritis caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline.</p>	<p>Feed in appropriate ration to provide from 8 to 20 mg per pound of body weight per day depending upon age and severity of disease. Feed for not more than 21 days.</p>
	<p><b>200-400 g/ton</b>            Control and treatment of viral enteritis caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline.</p>	<p>Feed in appropriate ration to provide from 8 to 20 mg per pound of body weight per day depending upon age and severity of disease. Feed for not more than 21 days.</p>
<b>SHEEP</b>	<p><b>CAUTION:</b> FOR USE IN DRY FEED ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS.</p> <p><b>20-40 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p>	<p><b>20 mg/ton/day</b>  <b>REDUCED P-DEEP:</b> Reduction in the incidence of (bacterial) enteritis caused by <i>Cherrylin</i> <i>Enter. faecalis</i> susceptible to chlorotetracycline.</p>
	<p><b>20-40 g/ton</b>            Increased rate of weight gain and improved feed efficiency.</p>	<p><b>20 mg/ton/day</b>  <b>REDUCED P-DEEP:</b> Reduction in the incidence of (bacterial) enteritis caused by <i>Cherrylin</i> <i>Enter. faecalis</i> susceptible to chlorotetracycline.</p>
<b>OSTRACHER BIRDS</b>	<p><b>WARNING:</b> POTENTIALLY AVOID CHLAMYDIA, OR A PATHOGEN TO A PREVENTABLE CONJUGATIVE DISEASE, TRANSMITTABLE BETWEEN WILD QUACKING BIRDS, OTHER BIRDS AND MAN. CONTACT APPROPRIATE PUBLIC HEALTH AND REGULATORY OFFICIALS.</p> <p><b>CAUTION:</b> ASPERGILLOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT.</p> <p><b>Plasma, Mucosa, Cloacal</b></p> <p><b>10 mg/Lb. feed</b>            Treatment of proctitis due to <i>Chlamydia</i>, mucosa, cloacal, and/or of tracheitis in the throat with proctitis caused by <i>Chlamydia</i> proctitis susceptible to chlorotetracycline. Feed continuously for 45 days.</p>	<p>Each bird should consume an amount of medicated feed equal to one-third of its body weight daily. During treatment, protein, vitamins, and minerals should be kept individually at its level in other cases.</p>
	<p><b>10 mg/Lb. feed</b>            Treatment of proctitis due to <i>Chlamydia</i>, mucosa, cloacal, and/or of tracheitis in the throat with proctitis caused by <i>Chlamydia</i> proctitis susceptible to chlorotetracycline. Feed continuously for 45 days.</p>	<p>Each bird should consume an amount of medicated feed equal to one-third of its body weight daily. During treatment, protein, vitamins, and minerals should be kept individually at its level in other cases.</p>

Pat. No. 2,812, 282 and  
 Patent Pending  
 Roche Vitamins Inc. New  
 Brunswick, New Jersey  
 07102-0000



Manufactured by:  
**Roche Vitamins Inc.**  
 Parsippany, New Jersey 07654

TAKE TIME



OBSERVE LABEL  
 DIRECTIONS

# AUREOMYCIN® 100 GRANULAR

TYPE A MEDICATED ARTICLE

## AUREOMYCIN® 100

chlortetracycline  
GRANULAR  
TYPE A MEDICATED ARTICLE  
FOR USE IN THE MANUFACTURE OF ANIMAL FEEDS

ACTIVE DRUG INGREDIENT: Chlortetracycline sodium complex equivalent to 100 g chlortetracycline HCl/Lb.

DISPENSING: Debiel Bioproteinose Association Fermentation Product and Children Tablets.

USE INSTRUCTIONS: Mix artificial AUREOMYCIN 100 Granular Medicated Article to supply desired concentration of chlortetracycline per ton with part of the feed ingredients to make a product. Add the remainder of the ingredients and mix thoroughly.

Level Desired, g/ton	Amount of Medicated Article per Ton
50	1/2 LB. †
100	1 LB.
200	2 LB.
400	4 LB.
500	5 LB.

† It is recommended that 1 pound of AUREOMYCIN 100 Granular Type A Medicated Article be added with 1 pound of one of the feed ingredients to have a 4 pound working premix. Use 2 pounds of the working premix to make a product from ONE HUNDRED (100) lbs of a Type C feed containing 20 g AUREOMYCIN chlortetracycline / ton of feed.

For specific use levels, see INDICATIONS.

### INDICATIONS

<b>CATTLE</b>	<p>WARNING: A WITHDRAWAL PERIOD HAS NOT BEEN ESTABLISHED FOR THIS PRODUCT IN PRE-RUMINATING CALVES. DO NOT USE IN CALVES TO BE PROCESSED FOR MEAT.</p> <p>CAUTION: FOR USE IN DRY FEED ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS.</p> <p>0.1 mg/Lb. body weight/day CALVES (50 TO 200 LB.): Increased rate of weight gain and improved feed efficiency.</p> <p>0.5 mg/Lb. body weight/day BEEF CATTLE (OVER 700 LB.): Control of active infection of septicemia caused by <i>Amphibacillus marshallii</i> susceptible to chlortetracycline.</p> <p>0.5 to 1.0 mg/Lb. body weight/day BEEF AND NON-LACTATING BARRY CATTLE (OVER 700 LB.): Control of active infection of septicemia caused by <i>Amphibacillus marshallii</i> susceptible to chlortetracycline when delivered in a free-choice feed. Free-choice feed must be manufactured under a feed mill license at 100 mg/Lb. body weight/day.</p> <p>10 mg/Lb. body weight/day CALVES, BEEF AND NON-LACTATING BARRY 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.</p>	<p>0.5-70 mg/Lb. body weight/day CALVES (50 TO 400 LB.): Increased rate of weight gain and improved feed efficiency.</p> <p>70 mg/Lb. body weight/day GROWING CATTLE (OVER 400 LB.): Increased rate of weight gain and improved feed efficiency, and reduction of liver condemnation due to liver abscesses.</p> <p>200 mg/Lb. body weight/day BEEF CATTLE: Control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.</p> <p>BEEF CATTLE (OVER 700 LB.): Control of active infection of septicemia caused by <i>Amphibacillus marshallii</i> susceptible to chlortetracycline.</p>
	<b>SWINE</b>	<p>10-50 g/ton Increased rate of weight gain and improved feed efficiency.</p> <p>50-100 g/ton Reduction in the incidence of cervical lymphadenitis (swell abdomen) caused by Group E. <i>Streptococcus</i> susceptible to chlortetracycline.</p>
<b>CHICKENS</b>	<p>10-50 g/ton Increased rate of weight gain and improved feed efficiency.</p> <p>100-200 g/ton Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p> <p>400 g/ton Control of hemorrhagic caused by <i>Haemophilus meleagridis</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p>100-400 g/ton 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.</p> <p>800 g/ton Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days.</p>
<b>TURKEYS</b>	<p>WARNING: NOT TO BE FED TO TURKEYS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p>10-50 g/ton Increased rate of weight gain and improved feed efficiency.</p> <p>500 g/ton Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p> <p>400 g/ton Control of hemorrhagic caused by <i>Haemophilus meleagridis</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>	<p>400 g/ton TURKEY POULTS NOT OVER 4 WEEKS OF AGE: Reduction of mortality due to <i>Escherichia coli</i> caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.</p> <p>50 mg/Lb. body weight/day Control of conjunctivitis bacterial organisms associated with bluecomb syndrome enteritis, conjunctivitis enteritis susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
<b>DUCKS</b>	<p>WARNING: NOT TO BE FED TO DUCKS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p>500-600 g/ton Control and treatment of liver cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.</p>	<p>Feed in one dose twice to provide from 8 to 20 mg per pound of body weight per day depending upon age and severity of disease. Feed for not more than 21 days.</p>
<b>SHEEP</b>	<p>CAUTION: FOR USE IN DRY FEED ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS.</p> <p>50-500 g/ton Increased rate of weight gain and improved feed efficiency.</p>	<p>50 mg/Lb. body weight/day SHEEPING SHEEP: Reduction in the incidence of (vibriosis) enteritis caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.</p>
<b>PSITTACINE BIRDS</b>	<p>WARNING: PSITTACOSIS, AVIAN CHLAMYDIOSIS, OR ORNITHOSIS IS A REPRODUCTION CAPABLE DISEASE, TRANSMISSIBLE BETWEEN WILD AND DOMESTIC BIRDS, OTHER ANIMALS AND MAN. CONTACT APPROPRIATE PUBLIC HEALTH AND REGULATORY OFFICIALS.</p> <p>CAUTION: ASPERGILLIOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT:</p> <p>Parrots, Macaws, Cockatoos</p> <p>10 mg/Lb. feed Treatment of psittacosis (parrot, macaw, cockatoo) associated or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> susceptible to chlortetracycline. Feed continuously for 45 days.</p>	<p>Each bird should consume an amount of medicated feed equal to one 1/16th of its body weight daily. During treatment, parrots, macaws, and cockatoos should be kept individually or in pairs in clean cages.</p>

Net Wt. 100 Lb. 22.7 kg  
Product of Debiel Bioproteinose  
Association Fermentation  
Product and Children Tablets  
Manufactured from the dry mix  
of ingredients



Manufactured by:  
**Roche Vitamins Inc.**  
Parlappany, New Jersey 07354

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