

JUL 3 1 1998

Date of Approval: _____

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: Deletion of limitations statement, "Do not feed to chickens producing eggs for human consumption" and establishment of a Tolerance for **chlortetracycline** in eggs.

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:

Dosage

Indication for use

CHICKENS

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 **Mycoplasma synoviae** 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

Withdraw 24 hours prior to slaughter.

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 an ADI (ADI) of 0.025 mg/kg of body weight (bw) per day, reserving 60% of the ADI for milk and eggs, unified tolerances of 2 ppm for muscle, 6 ppm for liver and 12 ppm for kidney and fat now are codified for total tetracycline residues (i.e., tetracycline, oxytetracycline and chlortetracycline). The ADI for milk and eggs is calculated as follows:

$$\text{ADI for Milk and Eggs} = 0.025 \text{ mg/kg bw /day} \times 0.60 = 0.015 \text{ mg/ kg bw / day}$$

Using the above ADI, reserving 50% of the nontissue ADI for eggs, and applying the current consumption factors, the tolerance for total tetracycline in eggs is calculated as follow:

$$\text{Tolerance for total Tetracycline in Eggs} = \frac{0.0075 \text{ mg/ kg bw /day} \times 60 \text{ kg}}{0.1 \text{ kg/ day}} = 4.5 \text{ ppm}$$

While the toxicology data would support a tolerance as high as 4.5 ppm for eggs, we are unable to build a relationship between this tolerance value and

Study Director: PE Gingher
Study Location: American Cyanamid Company
Agricultural Research Division
Princeton, NJ 08540

Twenty White Leghorn laying hens were treated with 120 ppm CTC in the drinking water for seven consecutive days. Ten birds served as untreated controls. Eggs were collected from the treated birds from 0 through 12 days withdrawal and assayed **microbiologically** for residues of CTC. Eggs from control birds were assayed for CTC on days 0 and 5 of the withdrawal period. Eggs were assayed in order of collection until residues at two consecutive withdrawal days were less than 0.05 ppm. The study results are summarized in Table 2.

Table 2: Mean residues (ppm) of CTC in whole eggs from laying hens treated with 120 ppm CTC in the drinking water for seven consecutive days.

Withdrawal (days)	Treatment Group	
	Controls	CTC, 120 ppm
0	Negative*	Neg. -0.041
1	**	Neg. -0.041
2	**	Negative
3	**	Negative
4	**	Negative
5	Negative	Negative

* Negative= activity <0.0375 ppm ** Not assayed

C. Confirming zero withdrawal for eggs

The reported residues in the eggs of treated hens are generally low. In the feeding study, birds were dosed at 60% of the maximum labeled dose. If residues for the study are corrected to the maximum codified dose of 500 ppm, they would range from negative to 0.07 ppm. In the drinking water study, birds were dosed at 45% of the maximum labeled dose. If residues for the study are corrected to the maximum codified dose of 1000 mg/gallon (263 ppm), they would range from negative to 0.09 ppm.

The 99th percentile/95% confidence intervals were calculated for residues of chlortetracycline administered *via* feed and water. For feed administration, the upper confidence limit is 90 ppb for untransformed data and 95 ppb for log transformed data. For drinking water administration, the upper confidence limit is 105 ppb for untransformed data and 106 ppb for log transformed data.

For both studies, residues in eggs at zero withdrawal are well below the tolerance of 400 ppb.

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 Type A Medicated Article in the treatment of chickens producing eggs for human consumption and the establishment of a tolerance for chlortetracycline in eggs (0.4 ppm).

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. 10f] 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 re-evaluation of the human food safety data in the parent application.

Under the Generic Animal Drug and Patent Term Restoration Act of 1988, this supplemental approval for food producing animal qualifies for THREE years of marketing exclusivity beginning on the date of approval under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(c)(2)(F)(iii)] because the supplemental application contains reports of new

human food safety studies (establishing the tolerance for eggs) essential to the approval of the application and conducted by the sponsor.

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

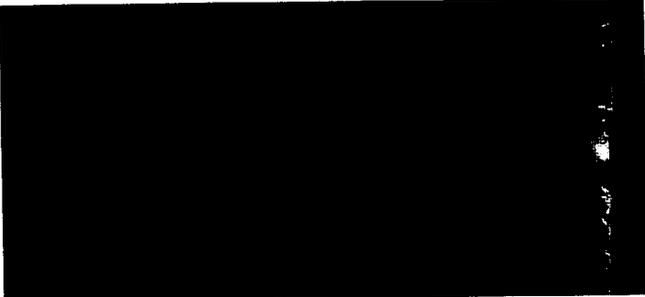
Aureomycin[®] 50, 90, and 100 premix bags

AUREOMYCIN® 50
 GRANULAR
 TYPE A MEDICATED ARTICLE



AUREOMYCIN® 50
 chlortetracycline
GRANULAR
 TYPE A
 MEDICATED ARTICLE

FOR USE IN THE MANUFACTURE OF ANIMAL FEEDS



AUREOMYCIN® 50
 GRANULAR
 TYPE A MEDICATED ARTICLE

AUREOMYCIN® 50
 chlortetracycline
GRANULAR
 TYPE A MEDICATED ARTICLE
 FOR USE IN THE MANUFACTURE OF ANIMAL FEEDS

Level of medication	Amount of medication
100%	100 Gm. (1 lb.)
50%	50 Gm. (1 lb.)
25%	25 Gm. (1 lb.)
12.5%	12.5 Gm. (1 lb.)
6.25%	6.25 Gm. (1 lb.)
3.125%	3.125 Gm. (1 lb.)

1. In a medicated feed, 1 pound of chlortetracycline 50 Granular Type A medicated article is diluted with 4 pounds of one of the feed ingredients listed in the following table. The amount of one of the feed ingredients to be added to the feed is 100 Gm. (1 lb.) of the feed ingredient listed in the following table. The amount of chlortetracycline 50 Granular Type A medicated article to be added to the feed is 100 Gm. (1 lb.) of the medicated article.

INDICATIONS

INDICATIONS	Directions
CATTLE	<p>Indicated for the treatment of respiratory tract infections, mastitis, metritis, and other infections of the genital tract. Also indicated for the treatment of enteric infections, such as salmonellosis, and for the treatment of skin infections, such as pyoderma.</p> <p>Directions: Feed 100 Gm. (1 lb.) of chlortetracycline 50 Granular Type A medicated article daily for 7 to 14 days.</p>
SWINE	<p>Indicated for the treatment of respiratory tract infections, mastitis, metritis, and other infections of the genital tract. Also indicated for the treatment of enteric infections, such as salmonellosis, and for the treatment of skin infections, such as pyoderma.</p> <p>Directions: Feed 100 Gm. (1 lb.) of chlortetracycline 50 Granular Type A medicated article daily for 7 to 14 days.</p>
CHICKENS	<p>Indicated for the treatment of respiratory tract infections, mastitis, metritis, and other infections of the genital tract. Also indicated for the treatment of enteric infections, such as salmonellosis, and for the treatment of skin infections, such as pyoderma.</p> <p>Directions: Feed 100 Gm. (1 lb.) of chlortetracycline 50 Granular Type A medicated article daily for 7 to 14 days.</p>
TURKEYS	<p>Indicated for the treatment of respiratory tract infections, mastitis, metritis, and other infections of the genital tract. Also indicated for the treatment of enteric infections, such as salmonellosis, and for the treatment of skin infections, such as pyoderma.</p> <p>Directions: Feed 100 Gm. (1 lb.) of chlortetracycline 50 Granular Type A medicated article daily for 7 to 14 days.</p>
DUCKS	<p>Indicated for the treatment of respiratory tract infections, mastitis, metritis, and other infections of the genital tract. Also indicated for the treatment of enteric infections, such as salmonellosis, and for the treatment of skin infections, such as pyoderma.</p> <p>Directions: Feed 100 Gm. (1 lb.) of chlortetracycline 50 Granular Type A medicated article daily for 7 to 14 days.</p>
SHEEP	<p>Indicated for the treatment of respiratory tract infections, mastitis, metritis, and other infections of the genital tract. Also indicated for the treatment of enteric infections, such as salmonellosis, and for the treatment of skin infections, such as pyoderma.</p> <p>Directions: Feed 100 Gm. (1 lb.) of chlortetracycline 50 Granular Type A medicated article daily for 7 to 14 days.</p>
PASTURE BIRDS	<p>Indicated for the treatment of respiratory tract infections, mastitis, metritis, and other infections of the genital tract. Also indicated for the treatment of enteric infections, such as salmonellosis, and for the treatment of skin infections, such as pyoderma.</p> <p>Directions: Feed 100 Gm. (1 lb.) of chlortetracycline 50 Granular Type A medicated article daily for 7 to 14 days.</p>

For information on the use of Aureomycin 50 Granular Type A medicated article, consult the directions on the label.

Roche Vitamins Inc.
 Parsippany, New Jersey 07654

TAKE TIME

 OBSERVE LABEL
 DIRECTIONS

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 *Streptomyces aureofaciens* Fermentation Product and Calcium Sulfate.

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.

Level Desired, g/ton	Amount of Medicated 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 w 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 feed containing 10 g AUREOMYCIN chlortetracycline / ton of feed.

INDICATIONS

	WITH CAUT	VEAL CALVES
CATTLE	mg/Lb. body proved 250 0.8 mg/Lb. body weight/day D EEP CATTLE (OVER 700 LB.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline. 0.8 to 2.0 mg/Lb. body weight/day 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. 10 mg/Lb. body weight/day CALVER, 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 6 days.	mg/head/day crossed 75 and/day GROWING CATTLE (OVER 400 LB.): Increased rate of weight gain and improved feed efficiency, and reduction of liver condemnation due to liver abscesses. 350 mg/head/day 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.
	SWINE	400 g/ton BREEDING SWINE: Control of leptospirosis (reducing the incidence of abortion and shedding of leptospires) caused by <i>Leptospira</i> , <i>mot</i> susceptible to chlortetracycline. Feed continuously for not more than 14 days. 10 mg/Lb. body weight/day 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.
CHICKENS	10-50 g/ton Increased rate of weight gain and improved feed efficiency. 100-200 g/ton Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	200-400 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. 500 g/ton Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. Feed for 5 days. WARNING: Withdraw 24 Hours Prior to Slaughter
TURKEYS	WARNING: NOT TO BE FED TO TURKEYS PRODUCING EGGS FOR HUMAN CONSUMPTION. 10-50 g/ton Increased rate of weight gain and improved feed efficiency. 200 g/ton Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days. 400 g/ton Control of hepatitis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.	400 g/ton TURKEY POULTS NOT OVER 4 WEEKS OF AGE: Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline. 25 mg/Lb. body weight/day Control of complicating bacterial organisms associated with bluecomb (paratyphoid enteritis; coronaviral enteritis) susceptible to chlortetracycline. Feed continuously for 7 to 14 days.
DUCKS	WARNING: NOT TO BE FED TO DUCKS PRODUCING EGGS FOR HUMAN CONSUMPTION. 200-400 g/ton Control and treatment of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	Feed in complete 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.
SHEEP	CAUTION: FOR USE IN DRY FEED ONLY. NM FGF! USE IN LIQUID TYPE MEDICATED FEEDS. 20-50 g/ton Increased rate of weight gain and improved feed efficiency.	50 mg/head/day BREEDING SHEEP: Reduction in the incidence of (vibriotic) abortions caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.
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: ASPERGILLIOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT. Parrots, Macaws, Cockatoos 10 mg/g feed 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 46 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.

TAKE TIME



Net Wt. 50 Lb. (22.7 kg)
Product Code 9404172907
Batch No.: See bag seal



Manufactured for:

Roche Vitamins I n COBSERVE LABEL

AUREOMYCIN® 90

chlortetracycline

GRANULAR

TYPE A MEDICATED ARTICLE

FOR USE IN THE MANUFACTURE OF ANIMAL FEEDS

ACTIVE DRUG INGREDIENT: Chlortetracycline calcium complex equivalent to 90 g chlortetracycline HCl/b.

INGREDIENTS: Dried *Streptomyces aureofaciens* Fermentation Product and Calcium Sulfate.

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.

Level Desired, g/ton	Amount of Medicated Article per Ton
50	Box [†]
100	1 Lb. 20z.
200	2 Lb. 4 oz.
400	4 Lb. 8 oz.
500	5 Lb. 9 oz.

† 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 50g AUREOMYCIN chlortetracycline/ton of feed.

INDICATIONS

CATTLE	<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 VEAL.</p> <p>CAUTION: FOR USE IN DRY FEED ONLY. NOT FOR USE IN LIQUID TYPE MEDICATED FEEDS.</p> <p>0.1 mg/Lb. body weight/day CALVES (UP TO 250 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 anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.</p> <p>1.0 mg/Lb. body weight/day 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.</p> <p>10 mg/Lb. body weight/day 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.</p>	<p>25-70 mg/head/day CALVES (250 TO 400 LB.): Increased rate of weight gain and improved feed efficiency.</p> <p>70 mg/head/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>500 mg/head/day SEEF CATTLE: Control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.</p> <p>BEEF CATTLE (UNDER 700 LB.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.</p>
	SWINE	<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 (owl abscesses) caused by Group E. <i>Streptococci</i> susceptible to chlortetracycline.</p>
CHICKENS		<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>
	TURKEYS	<p>10-50 g/ton Increased rate of weight gain and improved feed efficiency.</p> <p>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 hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
DUCKS		<p>WARNING: NOT TO BE FED TO DUCKS PRODUCING EGGS FOR HUMAN CONSUMPTION.</p> <p>200-400 g/ton Control and treatment of owl cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.</p>
	SHEEP	<p>CAUTION: FOR USE IN DRY FEED ONLY. NOT FOR USE IN LIQUID TYPE MEDICATED FEEDS.</p> <p>20-50 g/ton Increased rate of weight gain and improved feed efficiency.</p>
PSITTACINE BIRDS		<p>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.</p> <p>CAUTION: ASPERGILLIOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT.</p> <p>Parrots, Macaws, Cockatoos</p> <p>10 mg/g P/d 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.</p>

AUREOMYCIN[®] 100

chlortetracycline
GRANULAR

TYPE A MEDICATED ARTICLE

FOR USE IN THE MANUFACTURE OF ANIMAL FEEDS

ACTIVE DRUG INGREDIENT: Chlortetracycline calcium complex equivalent to 100 g chlortetracycline H₂O/Lb.

INGREDIENTS: Dried *Streptomyces aureofaciens* Fermentation Product and Calcium Sulfate.

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.

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 diluted with 3 pounds of one of the feed ingredients to form a 4 pound working preblend. Use 2 pounds of the working preblend to make a preblend (see USE DIRECTIONS) for a Type C feed containing 50 g AUREOMYCIN chlortetracycline / ton of feed.

INDICATIONS

CATTLE	<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 VEAL.</p> <p>CAUTION: FOR USE IN DRY FEED ONLY. NOT FOR GROSS IN LIQUID TYPE B MEDICATED FEEDS.</p> <p>1. 10 mg/Lb. body weight/day CALVES (UP TO 250 LB.): Increased rate of weight gain and improved feed efficiency.</p> <p>2. 5 mg/Lb. body weight/day BEEF CATTLE (OVER 700 LB.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.</p> <p>3. 5 to 2.0 mg/Lb. body weight/day BEEF AND NON-LACTATING DAIRY CATTLE (OVER 750 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.</p> <p>4. 10 mg/Lb. body weight/day 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.</p>	<p>5. 25-75 mg/head/day CALVES (250 TO 400 LB.): Increased rate of weight gain and improved feed efficiency.</p> <p>6. 7 mg/head/day GROWING CATTLE (OVER 400 U.): 11-1cdrd901 weight gain and improved feed efficiency, and reduction of liver condemnation due to liver abscesses.</p> <p>7. 350 mg/head/day SSEF CATTLE: Control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.</p> <p>8. BEEF CATTLE (UNDER 700 LB.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.</p>	
	SWINE	<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 (Jowl abscesses) caused by Group E. <i>Streptococci</i> susceptible to chlortetracycline.</p>	<p>400 g/ton BREEDING PIGS: 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.</p> <p>10 mg/Lb. body weight/day 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 4 days.</p>
		CHICKENS	<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>
TURKEYS	<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>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 tenosynovitis caused by <i>Haemophilus</i> susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>		<p>400 g/ton TURKEY POULTS - OVER 4 WEEKS OF AGE: Reduction of mortality due to peritonitis caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.</p> <p>25 mg/Lb. body weight/day Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronavirus enteritis) susceptible to chlortetracycline. Feed continuously for 7 to 14 days.</p>
	DUCKS	<p>WARNING: NOT TO BE FED TO PRODUCE EGGS FOR HUMAN CONSUMPTION.</p> <p>200-400 g/ton Control and treatment of fowl 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>
SHEEP		<p>CAUTION: FOR USE IN DRY FEED ONLY. NOT FOR LWS IN LIQUID TYPE B MEDICATED FEEDS.</p> <p>20-50 g/ton Increased rate of weight gain and improved feed efficiency.</p>	<p>80 mg/head/day BREEDING SHEEP: Reduction in the incidence of (vibriotic) abortions caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.</p>
	BIRDS PSITTACINE	<p>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.</p> <p>CAUTION: ASPERGILLIOSIS MAY OCCUR FOLLOWING PROLONGED TREATMENT.</p> <p>Parrots, Macaws, Cockatoos</p> <p>10 mg/g feed 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 for 14 days.</p>	<p>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 sawdust.</p>

Net Wt.: 40 Lb. (22.7 kg)
Product Code: 0444210807
Batch No.: See bag seal
— Public Use Bag seal

Manufactured for:
Roche Roche Vitamins
Parippany, New Jersey 07050

TAKE TIME



INC. OBSERVE LABEL
DIRECTIONS