

Date of Approval: FEB 28 2006

FREEDOM OF INFORMATION SUMMARY

Supplemental New Animal Drug Application

NADA 138-935

PENNCHLOR Type A Medicated Article
(chlortetracycline)

To provide for a change in the withdrawal time for cattle from one day to zero days.

Sponsored by:
Pennfield Oil Co.

2006-138-935

FOIS 2

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1. GENERAL INFORMATION:

- a. File Number: NADA 138-935
- b. Sponsor: Pennfield Oil Company
14040 Industrial Rd.
Omaha, NE 68144
Drug Labeler Code: 048164
- c. Established Name: Chlortetracycline
- d. Proprietary Name: PENNCHLOR Type A Medicated Article
- e. Dosage form: Type A medicated article
- f. How Supplied: 50 pound bag
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 50, 90, and 100 g/pound
- i. Route of Administration: Oral – Mixed in feed
- j. Species/Class: Cattle, swine, sheep, chickens, and turkeys
- k. Recommended Dosage: Cattle – 25 to 350 mg/head/day (0.1, 0.5, and 10 mg/lb body weight [BW]/day)
Swine – 10 to 400 grams/ton (10 mg/lb BW/day)
Sheep – 20 to 50 grams/ton (80 mg/head/day)
Chickens – 10 to 500 grams/ton
Turkeys – 10 to 500 grams/ton (25 mg/lb BW/day)
- l. Pharmacological Category: Antimicrobial
- m. Indications: Cattle:
Calves, beef cattle, and nonlactating dairy cattle.
For Calves (up to 250 lbs) – For an increased rate of weight gain and improved feed efficiency.
For Calves (250-400 lbs) – For an increased rate of weight gain and improved feed efficiency.
For Growing Cattle (over 400 lbs.) - For an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.
For Beef Cattle – For the control of bacterial

pneumonia associated with shipping fever complex caused by Pasteurella spp. susceptible to chlortetracycline.

For Beef Cattle (under 700 lbs.) – Control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline.

For Beef Cattle (over 700 lbs.) – Control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline.

For Calves, Beef, and Nonlactating Dairy Cattle – For treatment of bacterial enteritis caused by Escherichia coli and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline. (Treat for not more than 5 days)

Sheep:

For Growing Sheep – For an increased rate of weight gain and improved feed efficiency.

For Breeding Sheep - Reducing the incidence of (vibriotic) abortion caused by Campylobacter fetus infection susceptible to chlortetracycline.

Swine:

For Growing Swine – For an increased rate of weight gain and improved feed efficiency.

For Swine - Reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci susceptible to chlortetracycline.

For Breeding Swine - Control of leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by Leptospira pomona susceptible to chlortetracycline. (Feed continuously for 14 days)

For Swine - Treatment of bacterial enteritis caused by Escherichia coli and Salmonella cholerasuis and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline. (Feed for not more than 14 days)

Chickens:

For Broiler/fryer chickens: For an increased rate of weight gain and improved feed efficiency.

For Chickens - Control of infectious synovitis

caused by Mycoplasma synoviae susceptible to chlortetracycline. (Feed continuously for 7-14 days)

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

For Chickens - Reduction of mortality due to Escherichia coli infections susceptible to chlortetracycline. (Feed for 5 days)

Turkeys:

For Turkeys: Growing Turkeys – For an increased rate of weight gain and improved feed efficiency.

For Turkeys - Control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline. (Feed continuously for 7-14 days)

For Turkeys - Control of hexamitiasis caused by Hexamita meleagrides susceptible to chlortetracycline. (Feed continuously 7-14 days)

For Turkeys: Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by Salmonella typhimurium susceptible to chlortetracycline.

For Turkeys - Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline. (Feed continuously for 7-14 days)

n. Effect of Supplement:

To change the withdrawal time for cattle for PENNCHLOR Type A Medicated Article from one day to zero days.

2. EFFECTIVENESS:

No new effectiveness data were required for the approval of this supplement. The product's effectiveness was established in the original Freedom of Information (FOI) Summary dated February 16, 1996.

3. TARGET ANIMAL SAFETY:

No new target animal safety data were required for the approval of this supplement. The product's target animal safety was established in the original FOI Summary dated February 16, 1996.

4. HUMAN FOOD SAFETY:

a. Toxicology:

An Acceptable Daily Intake (ADI) of 25 µg/kg bodyweight/day has been established previously for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline under 21 CFR 556.150. The ADI is apportioned as 40% to tissues and 60% to milk.

An assessment was presented on the effects of chlortetracycline residues present in edible tissues of cattle on human intestinal flora. It was concluded that the amount of active chlortetracycline residues reaching the human colon following a zero-day withdrawal period for cattle probably will not have any adverse effect on human intestinal flora.

b. Residue Chemistry:

1. Summary of Residue Chemistry Studies

Tissue Residue Depletion Study of Chlortetracycline from Edible Tissues of Cattle Dosed with Pennchlor Type A Medicated Article at a Rate Equivalent to 10 mg of Chlortetracycline Hydrochloride Activity per Pound of Body Weight for 5 Days . Study No. C-0205. October 2002.

Study Director: Dan C. Ronning

Testing Facility: Colorado Animal Research Enterprises, Fort Collins, Colorado

The study was conducted in accordance with Good Laboratory Practices (GLPs as described in 21 CFR 58).

Commercial crossbred cattle derived from Angus and Hereford breeds were used. The animals were approximately 7 months old and ranged from 514 to 678

pounds body weight. The test group consisted of 6 steers and 6 heifers. The control group consisted of 1 steer and 1 heifer. The cattle were acclimated for 22 days prior to dosing. The test cattle were fed 11 mg chlortetracycline HCl activity/pound body weight/day for 5 days. Control animals received unmedicated basal feed. On study day 1, the control cattle were slaughtered by mechanical stunning and exsanguination. The test cattle were slaughtered after 5 days of treatment by electrocution and exsanguination. Residues of chlortetracycline in kidneys of each animal were measured using the regulatory method.

Chlortetracycline Levels in Kidney from Cattle Fed 11 mg chlortetracycline HCl activity/pound bodyweight/day for 5 days (n=1).		
Gender	Chlortetracycline Levels in ppm	Mean (standard deviation)
heifer	6.088	7.330 (2.988)
heifer	4.324	
heifer	10.678	
heifer	10.420	
heifer	3.898	
heifer	8.570	
steer	11.774	7.004 (3.096)
steer	8.162	
steer	4.431	
steer	6.713	
steer	2.979	
steer	7.965	
		Overall Mean 7.167 (2.906)

Pilot Tissue Residue Depletion Study of Chlortetracycline from Edible Tissues of Cattle Dosed with Pennchlor Type A Medicated Article at a Rate Equivalent to 10 mg of Chlortetracycline Hydrochloride Activity Per Pound of Body Weight for 5 Days. Study No. C-0305

Study Director: Dan C. Ronning

Testing Facility: Colorado Animal Research Enterprises, Fort Collins, Colorado

The study was not conducted in accordance with Good Laboratory Practices (GLPs as described in 21 CFR 58).

Four steers and four heifers (approximately one year old, body weight ranging from 728 to 878 pounds) were used as test animals. No control cattle were used. The cattle were fed 10.5 mg chlortetracycline HCl activity/lb body weight/day for 5 days. The cattle were slaughtered by electrocution and exsanguination after 5 days of treatment. Kidney samples were analyzed for chlortetracycline residues with the regulatory method.

2. Target Tissue and Marker Residue Assignment

Although a target tissue is not designated for chlortetracycline, residues deplete most slowly from kidney. Therefore, kidney was used to monitor the depletion of chlortetracycline in cattle in this study. Microbiologically active residues (parent drug plus metabolites) are measured with the method noted below.

3. Tolerance Assignment

Tolerances for chlortetracycline in edible tissue of cattle are established as 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney (21 CFR 556.150).

4. Withdrawal Times

A zero-day withdrawal time is supported by data in Study No. C-0205 and C-0305. Individual and mean chlortetracycline residue concentrations in kidney were below the 12 ppm tolerance.

c. Microbial Food Safety

A characterization of the potential microbial food safety hazard(s) attributable to the proposed change to a zero-day withdrawal time for the approved use of chlortetracycline in cattle was assessed. The Agency has determined that the proposed change from a one-day withdrawal time to a zero-day withdrawal time for the approved use of chlortetracycline in cattle does not, at this time, change the microbial food safety of this approved use of chlortetracycline.

d. Analytical Methods for Residues

1. Determinative Method

The regulatory method for detection of chlortetracycline residues is a cylinder-plate microbiological test.

2. Availability of Method

The validated regulatory method for detection of residues of chlortetracycline is available from the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

5. USER SAFETY:

Human warnings are provided on the product labeling as follows:

NOT FOR HUMAN USE

6. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that PENNCHLOR Type A Medicated Article, when used under its proposed conditions of use, is safe and effective for the labeled indications.

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

In accordance with 21 CFR 514.106(b)(2)(x), this is a Category II change. The safety and effectiveness data in the parent application did not need to be reevaluated. However, the approval did require a reevaluation of the human food safety data in the present application. The shorter withdrawal period was based on new data provided to the Agency.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food-producing animals does not qualify for marketing exclusivity because the application does not contain substantial evidence of the effectiveness of the drugs involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

No patents were submitted with this application.

6. ATTACHMENTS:

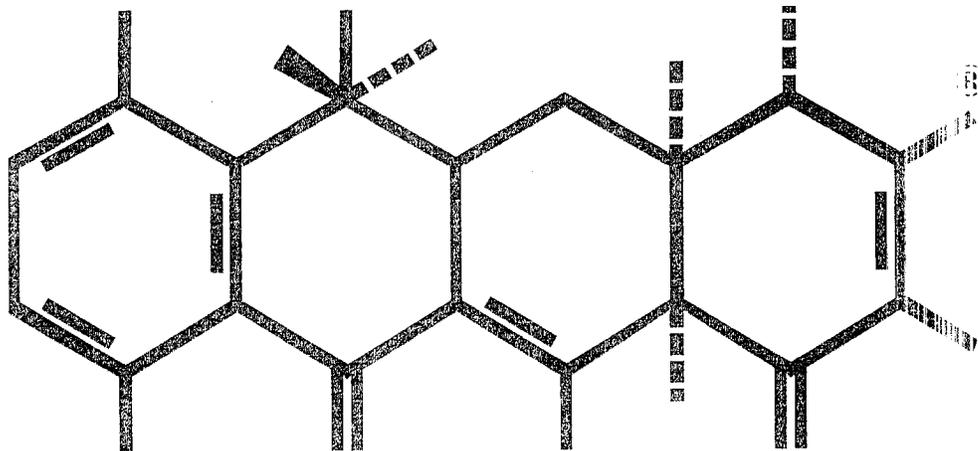
Facsimile labeling is attached as indicated below:

- a. PENNCHLOR 50 (chlortetracycline)Type A Medicated Article (Pennfield label)
- b. PENNCHLOR 50 G (chlortetracycline)Type A Medicated Article (Pennfield label)
- c. PENNCHLOR 50 (chlortetracycline)Type A Medicated Article (Durvet label)
- d. PENNCHLOR 50 G (chlortetracycline)Type A Medicated Article (Durvet label)
- e. PENNCHLOR 90 G (chlortetracycline)Type A Medicated Article (Pennfield label)
- f. PENNCHLOR 100 Hi-Flo (chlortetracycline)Type A Medicated Article (Pennfield label)
- g. PENNCHLOR 100 G (chlortetracycline)Type A Medicated Article (Pennfield label)

Pennchlor 5[®]

..... CHLORTETRACYCLINE

Type A Medicated Article



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 50 grams Chlortetracycline Hydrochloride, w. b.

INGREDIENTS:

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

CAUTION: For use in Dry Feeds ONLY – NOT FOR USE IN LIQUID FEED SUPPLEMENTS

NADA 138-935 APPROVED BY FDA

Restricted Drug (California)-

Use Only as Directed

NOT FOR HUMAN USE

NET WT.

50 lb (22.7 kg)

PennField[®]



Pennchlor 90

CHLOROTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Poultry/50 per ton	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 90 per ton
CHICKENS For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency. WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	19-50 g/ton	22-10	19-50 g/ton	0.28-1.0
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	100-200 g/ton	25-40	50-100 g/ton	1.0-2.0
For Chickens: 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 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	40-60	400 g/ton	8.0
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	10-0		
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency. WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	19-50 g/ton	0.2-1.0		
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	200 g/ton	4-0		
For Turkeys: Control of hematomas caused by <i>Streptococcus meleagridis</i> susceptible to chlorotetracycline. (Feed continuously 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	400 g/ton	6-0		
For Turkeys: Turkey poult (not over 4 weeks of age): Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlorotetracycline.	400 g/ton	8-0		
For Turkeys: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus) susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25mg/lb body weight/day			
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	29-50 g/ton	3-4-10		
For Breeding Sheep: Reducing the incidence of (hydropic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		80 mg/head/day		
For Calves (up to 250 lbs.): For an increased rate of weight gain and improved feed efficiency.			0.1 mg/lb body weight/day	
For Calves (250-400 lbs.): For an increased rate of weight gain and improved feed efficiency.			25-70 mg/head/day	
For Growing Cattle (over 400 lbs.): For an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.			70 mg/head/day	
For Beef Cattle: For the control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.			350 mg/head/day	
For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.			350 mg/head/day	
For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.			0.5mg/lb body weight/day	
For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Treat for not more than 5 days) WARNING: Zero-day withdrawal period.			10 mg/lb body weight/day	

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TAKE TIME  OBSERVE DIRECTIONS

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LURA-GRIP

Pennchlor

CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 50-G per ton	Indications for Use	Use Levels of Chlorotetracycline	Lbs. of Pennchlor 50-G per ton
CHICKENS For Broiler/fryer chickens: improved feed efficiency. WARNING: Do not feed to consuming birds during egg production. Zero-day withdrawal period.	10-50 g/ton	0.2-1.0	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency. For Swine: Reducing the incidence of cervical lymphadenitis (joint abscesses) caused by <i>Group E Streptococci</i> susceptible to chlorotetracycline.	10-50 g/ton	0.20-1.0
For Chickens: Control of infections caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. WARNING: Do not feed to consuming birds during egg production. Zero-day withdrawal period.	100-200 g/ton	0.4-0.8	For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	400 g/ton	8.0
For Chickens: Control of cholera infection caused by <i>Vibrio cholerae</i> susceptible to chlorotetracycline. WARNING: Do not feed to consuming birds during egg production. Zero-day withdrawal period.	200-400 g/ton	1.0-2.0	For Swine: 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 chlorotetracycline. (Feed for not more than 14 days) WARNING: Zero-day withdrawal period.		Feed approximately 400 g/ton varying with body weight and feed consumption to provide 10 mg/lb body weight/day
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections. WARNING: Do not feed to consuming birds during egg production. Withdraw 24 hours prior to slaughter.	500 g/ton	10.0	CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE 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.		
TURKEYS For Turkeys: Growing Turkeys and improved feed efficiency. WARNING: Do not feed to consuming turkeys during egg production. Zero-day withdrawal period.	10-50 g/ton	0.2-1.0	For Calves (up to 250 lbs.): For an increased rate of weight gain and improved feed efficiency. For Calves (250-400 lbs.): For an increased rate of weight gain and improved feed efficiency.		0.1 mg/lb body weight/day 25-70 mg/head/day
For Turkeys: Control of infections caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. WARNING: Do not feed to consuming turkeys during egg production. Zero-day withdrawal period.	200 g/ton	4.0	For Growing Cattle (over 400 lbs.): For an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.		70 mg/head/day
For Turkeys: Control of hexameter infections caused by <i>Hexameter mycophallidus</i> continuously (7-14 days). WARNING: Do not feed to consuming turkeys during egg production.	400 g/ton	8.0	For Beef Cattle: For the control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		350 mg/head/day
For Turkeys: Turkey poult mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> .	400 g/ton	8.0	For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		350 mg/head/day
For Turkeys: Control of conjunctivitis caused by bacterial organisms associated with bluecomb (transmissible venereal disease) and gonorrhea (transmissible venereal disease) susceptible to chlorotetracycline. (Feed continuously for 7-14 days). WARNING: Do not feed to consuming turkeys during egg production. Zero-day withdrawal period.	25 mg/lb body weight/day		For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		0.5 mg/lb body weight/day
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.4-1.0	For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Treat for not more than 5 days) WARNING: Zero-day withdrawal period.		10 mg/lb body weight/day
For Breeding Sheep: Reducing the incidence of (hyaline) abortion caused by <i>Campylobacter fetus</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		60 mg/head/day			



REV. 12/05
Bag X

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ANIMAL HEALTH

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Omaha, Nebraska 68144

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WEIGHT SHIPPING BAG
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DROSSE, ARKANSAS

DURA-GRIP

DURVET

38

NDC: 30798-373-56

Pennchlor[®] 50[™]

..... **CHLORTETRACYCLINE**



Type A Medicated Article

FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE INGREDIENTS:

Chlortetracycline hydrochloride, chlortetracycline calcium complex equivalent to 50 grams Chlortetracycline Hydrochloride/lb.

INGREDIENTS:

Chlortetracycline, Calcium Carbonate, Roughage Product and Mineral Oil.
See back panel for directions and warnings.

CAUTION: For use in Dry Feeds ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

NADA 138-935 APPROVED BY FDA



7 45801 10341 2

**Restricted Drug (California)-
Use Only as Directed
NOT FOR HUMAN USE**

**NET WT.
50 lb (22.7 kg)**

DURVET

**Manufactured for
DURVET, INC.
Blue Springs, Missouri 64014**

durvet

NDC: 30798-373-56

Pennchlor[®] TM

CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Pennchlor [®] 50 [™] Chlorotetracycline	lbs. of Pennchlor [®] 50 [™] per ton
CHICKENS: For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency. WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	10-50 g/ton	0.2-1.0
For Chickens: Control of infectious diseases caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	100-200 g/ton	2.0-4.0
For Chickens: Control of chronic respiratory disease (CRD) and associated infection caused by <i>Mycoplasma</i> spp. (<i>M. gallisepticum</i> and <i>Escherichia coli</i>) susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	4.0-8.0
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	10.0
TURKEYS: For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency. WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	10-50 g/ton	0.2-1.0
For Turkeys: Control of infectious arthritis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	200 g/ton	4.0
For Turkeys: Control of hemorrhagic disease caused by <i>Hexamita meleagridis</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	400 g/ton	8.0
For Turkeys: Turkey poult mortality - 1 weeks of age. Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlorotetracycline.	400 g/ton	8.0
For Turkeys: Control of complicated bacterial organisms associated with blackcomb (transmissible enteritis, coronaviral enteritis) susceptible to chlorotetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25 mg/lb body weight/day	
SHEEP: For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.4-1.0
For Breeding Sheep: Reducing the incidence of (vibrionic) abortion caused by <i>Campylobacter fetus</i> var. <i>faecalis</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	80 mg/head/day	

Indications for Use	Use Levels of Chlorotetracycline	lbs. of Pennchlor [®] 50 [™] per ton
SWINE: For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.2-1.0
For Swine: Reducing the incidence of cervical lymphadenitis (lump abscesses) caused by Group E <i>Streptococci</i> susceptible to chlorotetracycline.	50-100 g/ton	1.0-2.0
For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospires) caused by <i>Leptospira pomona</i> susceptible to chlorotetracycline. (Feed continuously for 14 days)	400 g/ton	8.0
For Swine: 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 chlorotetracycline. (Feed for not more than 14 days) WARNING: Zero-day withdrawal period.	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb body weight/day	
CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE: 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.		
For Calves (up to 250 lbs.): For an increased rate of weight gain and improved feed efficiency.	0.1 mg/lb body weight/day	
For Calves (250-400 lbs.): For an increased rate of weight gain and improved feed efficiency.	25-70 mg/head/day	
For Growing Cattle (over 400 lbs.): For an increased rate of improved weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.	70 mg/head/day	
For Beef Cattle: For the control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	350 mg/head/day	
For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	350 mg/head/day	
For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	0.5 mg/lb body weight/day	
For Calves, Beef, and Nonlactating Dairy Cattle: For 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) WARNING: Zero-day withdrawal period.	10 mg/lb body weight/day	

**CAUTION: For use in Dry Feeds ONLY.
NOT FOR USE IN LIQUID FEED SUPPLEMENTS**

TAKE TIME



OBSERVE LABEL DIRECTIONS

REV 12/05
Bag T

23114

9-03

FREIGHT SHIPPING BAG
Meeting requirements of
APPLICABLE FREIGHT CLASSIFICATION
Controlled by
BEMIS COMPANY, INC.
CROSSETT, ARKANSAS

DURA-GRIP[®]

durvet

Manufactured for
DURVET, INC.
Blue Springs, Missouri 64014

durvet

NDC: 30798-380-56

Pennchlor 50·G[®]

..... CHLORTETRACYCLINE



Type A Medicated Article

Patents Pending

FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE INGREDIENTS:

Chlortetracycline as Chlortetracycline calcium complex equivalent to 50 grams Chlortetracycline Hydrochloride/lb.

INGREDIENTS:

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.
See back panel for directions and warnings.

CAUTION: For use in Dry Feeds ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS.



Restricted Drug (California)-
Use Only as Directed

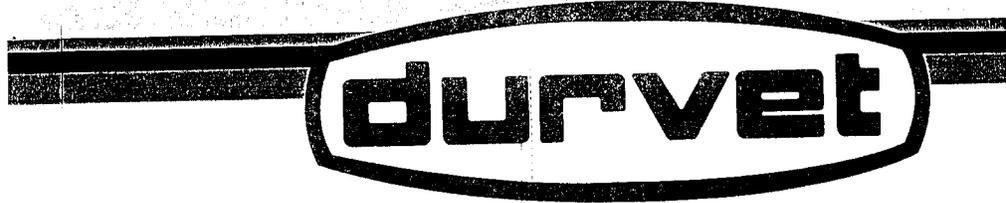
NOT FOR HUMAN USE

NET WT.

50 lb (22.7 kg)

durvet

Manufactured for
DURVET, INC.
Blue Springs, Missouri 64014



NDC: 30798-380-56

Pennchlor 50-G

CHLORTETRACYCLINE

DIRECTIONS FOR USE

Indications for Use	Use Levels of Chlortetracycline	lbs. of Pennchlor 50-G per ton
CHICKENS: For Broiler/layer chickens: For an increased rate of weight gain and improved feed efficiency. WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	10-50 g/ton	0.2-1.0
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	100-200 g/ton	2.0-4.0
For Chickens: 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 7-14 days) WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	4.0-8.0
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlortetracycline. (Feed for 5 days) WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	10.0
TURKEYS: For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency. WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	13-50 g/ton	0.2-1.0
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	200 g/ton	4.0
For Turkeys: Control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	400 g/ton	8.0
For Turkeys: Turkey poulters not over 4 weeks of age. Reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.	400 g/ton	8.0
For Turkeys: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to chlortetracycline. (Feed continuously for 7-14 days) WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	25 mg/lb body weight/day	
SHEEP: For Growing Sheep: For an increased rate of weight gain and improved feed efficiency.	20-50 g/ton	0.4-1.0
For Breeding Sheep: Reducing the incidence of tubercular abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline. WARNING: Zero-day withdrawal period.	80 mg/head/day	

Indications for Use	Use Levels of Chlortetracycline	lbs. of Pennchlor 50-G per ton
SWINE: For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.2-1.0
For Swine: Reducing the incidence of cervical lymphadenitis (owl abscesses) caused by Group E <i>Streptococcus</i> susceptible to chlortetracycline.	50-100 g/ton	1.0-2.0
For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospires) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline. (Feed continuously for 14 days)	400 g/ton	8.0
For Swine: 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) WARNING: Zero-day withdrawal period.		Feed approximately 400 g/l, varying with body weight and feed consumption to provide 10 mg/lb body weight/day
CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE: 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.		
For Calves (up to 250 lbs.): For an increased rate of weight gain and improved feed efficiency.		0.1 mg/lb body weight/day
For Calves (250-400 lbs.): For an increased rate of weight gain and improved feed efficiency.		25-70 mg/head/day
For Growing Cattle (over 400 lbs.): For an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.		70 mg/head/day
For Beef Cattle: For the control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella sp.</i> susceptible to chlortetracycline. WARNING: Zero-day withdrawal period.		350 mg/head/day
For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline. WARNING: Zero-day withdrawal period.		350 mg/head/day
For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline. WARNING: Zero-day withdrawal period.		0.5 mg/lb body weight/day
For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. (Feed for not more than 5 days) WARNING: Zero-day withdrawal period.		10 mg/lb body weight/day

CAUTION: For use in Dry Feeds ONLY.
NOT FOR USE IN LIQUID FEED SUPPLEMENTS

TAKE TIME



OBSERVE LABEL DIRECTIONS

REV 12/05
Bag TG

22150

6-03

FREIGHT SHIPPING BAG
Meeting requirements of
APPLICABLE FREIGHT CLASSIFICATION
Manufactured by
BEMIS COMPANY, INC.
CROSSETT, ARKANSAS

DURA-GRIP®



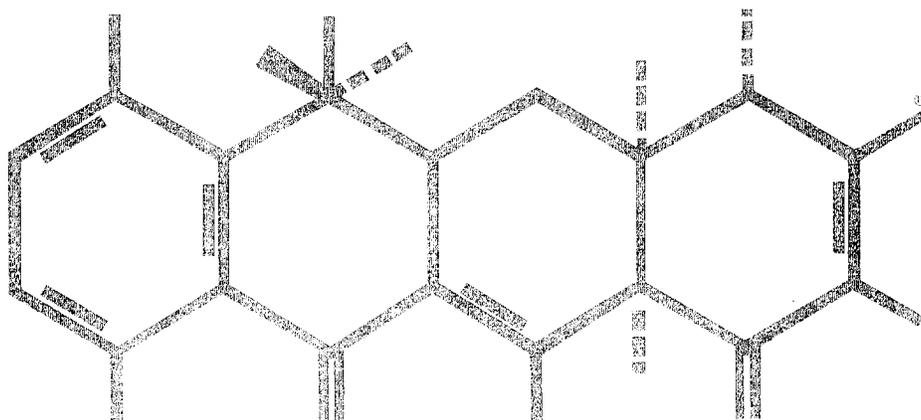
Manufactured for
DURVET, INC.
Blue Springs, Missouri 64014

Pennchlor[®]

CHLORTETRACYCLINE

Type A Medicated Article

Patents Pending



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:

Chlortetracycline as Chlortetracycline Calcium Complex equivalent to 90 grams Chlortetracycline Hydrochloride/lb.

INGREDIENTS:

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

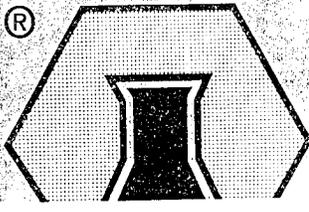
CAUTION: For use in Dry Feeds ONLY – NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

NADA 138-935 APPROVED BY FDA

Restricted Drug: (California) -
Use only as directed

NOT FOR HUMAN USE

**NET WT.
50 lb (22.7 kg)**

Pennfield[®] 

Pennchlor

CHLORTETRACYCLINE

DIRECTIONS FOR USE

43

Indications for Use	Use Levels of Chlorotetracycline	Percentage of 90G	Indications for Use	Use Levels of Chlorotetracycline	lbs. of Pennchlor 90G per ton
CHICKENS For Broiler/layer chickens: For improved feed efficiency. WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	10-50 g/ton	0.11-0.555	PORCINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency. For Swine: Reducing the incidence of cervical lymphadenitis (and abscesses) caused by <i>Group E Streptococci</i> susceptible to chlorotetracycline. For Breeding Swine: Control of leptospirosis (reducing the instances of abortions and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlorotetracycline. (Feed continuously for 14 days).	10-50 g/ton	0.11-0.555
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days). WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	100-200 g/ton	1.1-2.22	For Swine: Treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Campylobacter coli</i> susceptible to chlorotetracycline. (Feed for not more than 14 days). WARNING: Zero-day withdrawal period.	400 g/ton	4.44
For Chickens: 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 7-14 days). WARNING: Do not feed to chickens producing eggs for human consumption. Zero-day withdrawal period.	200-400 g/ton	2.22-4.44	CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE 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.		Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb body weight/day
For Chickens: Reduction of mortality due to <i>Escherichia coli</i> infections susceptible to chlorotetracycline. (Feed continuously for 7-14 days). WARNING: Do not feed to chickens producing eggs for human consumption. Withdraw 24 hours prior to slaughter.	500 g/ton	5.56	For Calves (up to 250 lbs.): For an increased rate of weight gain and improved feed efficiency. For Calves (250-400 lbs.): For an increased rate of weight gain and improved feed efficiency.		0.1 mg/lb body weight/day 25-70 mg/head/day
TURKEYS For Turkeys: Growing Turkeys: For an increased rate of weight gain and improved feed efficiency. WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	10-50 g/ton	0.11-0.555	For Growing Cattle (over 400 lbs.): For an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.		70 mg/head/day
For Turkeys: Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days). WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	220 g/ton	2.22	For Beef Cattle: For the control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella spp.</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		350 mg/head/day
For Turkeys: Control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlorotetracycline. (Feed continuously for 7-14 days). WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	400 g/ton	4.44	For Beef Cattle (under 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		550 mg/head/day
For Turkeys: Turkey poult mortality over 4 weeks of age. Reduction of mortality due to paratyphoid caused by <i>Campylobacter hyointestinalis</i> susceptible to chlorotetracycline.	400 g/ton	4.44	For Beef Cattle (over 700 lbs.): Control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.		0.5 mg/lb body weight/day
For Turkeys: Control of complications associated with bluecomb (transmissible enteritis, nonparatyphoid enteritis) susceptible to chlorotetracycline. (Feed continuously for 7-14 days). WARNING: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.	5 mg/lb body weight/day		For Calves, Beef, and Nonlactating Dairy Cattle: For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlorotetracycline. (Treat for not more than 5 days). WARNING: Zero-day withdrawal period.		10 mg/lb body weight/day
SHEEP For Growing Sheep: For an increased rate of weight gain and improved feed efficiency. For Breeding Sheep: Reducing the incidence of uterine infection caused by <i>Campylobacter fetus</i> susceptible to chlorotetracycline. WARNING: Zero-day withdrawal period.	10-50 g/ton	0.11-0.555			

TAKE TIME  OBSERVE DIRECTIONS

REV. 12/05
Bag YG

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Omaha, Nebraska 68144

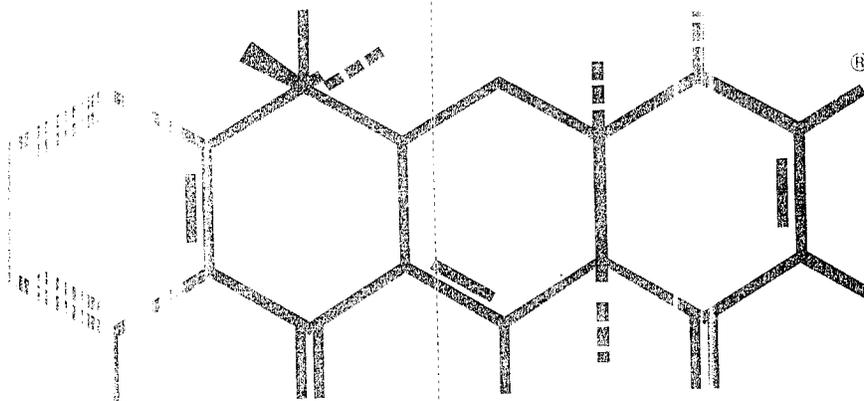
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FREIGHT SHIPPING BAG
Meeting requirements of
APPLICABLE FREIGHT CLASSIFICATION
Manufactured by
BEMIS COMPANY, INC.
CROSSETT, ARKANSAS

DURA-GRIP®

Chlortetracycline 100 Hi-FloTM

CHLORTETRACYCLINE

Type A Medicated Article



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:

Chlortetracycline Hydrochloride, Chlortetracycline Calcium Complex equivalent to 100 grams Chlortetracycline Hydrochloride/b.

INGREDIENTS:

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

CAUTION: For use in Dry Feeds ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

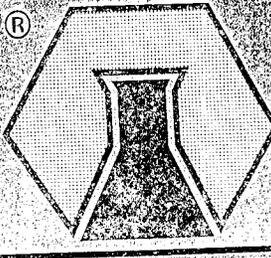
NADA 138-935 APPROVED BY FDA

Restricted Drug (California)-

Use Only as Directed

NOT FOR HUMAN USE

NET WT.
50 lb (22.7 kg)

Purina 

ANIMAL HEALTH

Pennchlor 100 Hi-Flo[®]

CHLORTETRACYCLINE

DIRECTIONS FOR USE

45

	Use Levels of Chlorotetracycline	lbs. of Pennchlor 100 Hi-Flo per ton	Indications for Use	Use Levels of Chlorotetracycline	lbs. of Pennchlor 100 Hi-Flo per ton
1. For an increased rate of weight gain and	10-14 g/ton	0.1-0.5	SWINE For Growing Swine: For an increased rate of weight gain and improved feed efficiency.	10-50 g/ton	0.10-0.5
2. Pigs producing eggs for human				50-100 g/ton	0.50-1.0
3. Pigs producing eggs for human				400 g/ton	4.0
4. Pigs producing eggs for human					Feed approximately 400 g/l, varying with body weight and feed consumption to provide 10 mg/lb body weight/day
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TAKE TIME TO OBSERVE DIRECTIONS

Rev. 12/05
Bag Z

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DURA-GRIP[®]

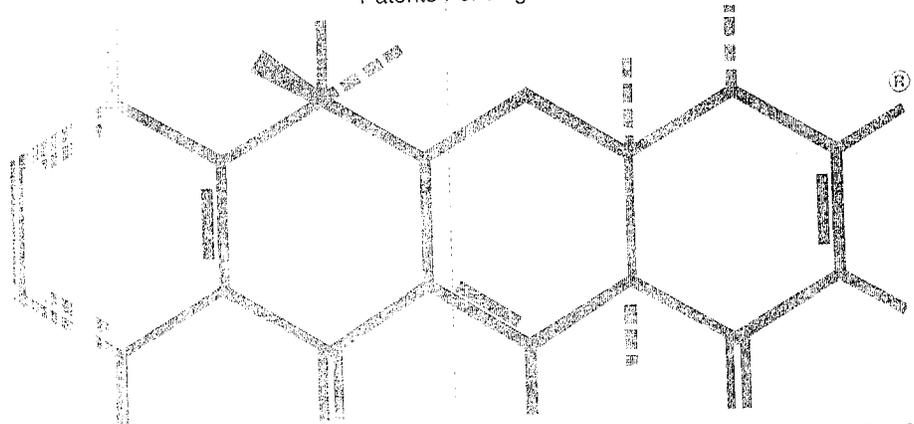
Pennchlor[®] 100·G[™]

CHLORTETRACYCLINE

45

Type A Medicated Article

Patents Pending



FOR USE IN THE MANUFACTURE OF MEDICATED FEEDS

ACTIVE DRUG INGREDIENTS:

Chlortetracycline is Chlortetracycline Calcium Complex equivalent to 100 grams Chlortetracycline Hydrochloride/lb.

INGREDIENTS:

Chlortetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.

See back panel for directions and warnings.

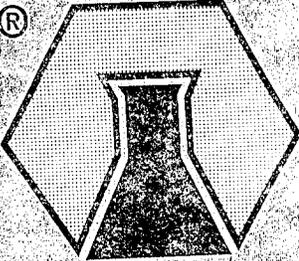
CAUTION: For use in Dry Feeds ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

NADA 138-935 APPROVED BY FDA

Restricted Drug: (California) -
Use only as directed

NOT FOR HUMAN USE

NET WT.
50 lb (22.7 kg)

Pennfield[®] 

ANIMAL HEALTH