

Date of Approval: FEB 10 1999

FREEDOM OF INFORMATION (FOI) SUMMARY

Oxytetracycline HCL Soluble Powder-343

For Chickens, Turkeys, Swine, Cattle, and Sheep

ANADA 200-247

Phoenix Scientific, Inc.

3915 South 48th Street Terrace

P.O. Box 6457

St. Joseph, MO 64506-0457

*ANADA 200-247*

*FOIS 1*

## FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION ANADA 200-247

ANADA/GENERIC SPONSOR-- Phoenix Scientific, Inc.  
3915 South 48th Street Terrace  
St. Joseph, MO 64506-0457

- a. Established Name: oxytetracycline hydrochloride
- b. Trade Name/Proprietary Name: OXYTETRACYCLINE HCL SOLUBLE POWDER-343
- c. Dosage Form: Soluble Powder for drinking water
- d. How Supplied: 9.6 oz foil pouches, 2 and 5 pound buckets
- e. How Dispensed: OTC
- f. Amount of Active Ingredients: Each pound contains oxytetracycline hydrochloride equivalent to 343 gram oxytetracycline hydrochloride
- g. Species: Chickens, Turkeys, Cattle, Swine, Sheep
- h. Labeled Dosage and Indications: (Refer to attached labeling for additional details on mixing instructions)

CHICKENS- INDICATIONS

DOSAGE

Control of infectious synovitis caused by *Mycoplasma synoviae* 200-400 mg/gal

Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* 400-800 mg/gal

Control of fowl cholera caused by *Pasteurella multocida* 400-800 mg/gal

TURKEYS - INDICATIONS DOSAGE

Control of Hexamitiasis 200-400 mg/gal  
caused by *Hexamita meleagridis*

Control of infectious synovitis 400 mg/gal  
caused by *Mycoplasma synoviae*

Growing Turkeys- Control of 25 mg/lb b.wt.  
complicating bacterial organisms  
associated with bluecomb  
(transmissible enteritis,  
coronaviral enteritis)

SWINE - INDICATIONS                      DOSAGE

FOR THE CONTROL AND 10 mg/lb body  
TREATMENT OF THE weight  
FOLLOWING DISEASES  
IN SWINE:

Bacterial enteritis caused by  
*Escherichia coli* and *Salmonella*  
*choleraesuis*, susceptible to  
oxytetracycline. Bacterial pneumonia  
caused by *Pasteurella multocida*,  
susceptible to oxytetracycline.

FOR BREEDING SWINE: 10 mg/lb body  
Leptospirosis (reducing the weight  
incidence of abortions and  
shedding of *Leptospira*) caused  
by *Leptospira pomona*, susceptible  
to oxytetracycline.

CATTLE - INDICATIONS                      DOSAGE

FOR THE CONTROL AND 10 mg/lb body  
TREATMENT OF THE weight  
FOLLOWING DISEASES  
IN CALVES, BEEF CATTLE  
AND NON-LACTATING  
DAIRY CATTLE:

Bacterial enteritis caused by  
*Escherichia coli* susceptible to

oxytetracycline. Bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*, susceptible to oxytetracycline.

SHEEP - INDICATIONS

DOSAGE

FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES:

10 mg/lb body weight

Bacterial enteritis caused by *Escherichia coli* susceptible to oxytetracycline. Bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*, susceptible to oxytetracycline.

**General Directions**

Mix fresh solutions daily. Use as sole source of oxytetracycline. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperature and humidity, each of which affects water consumption. Administer up to 14 days in swine, cattle, and sheep, and 7 to 14 days for chickens and turkeys.

i. Pioneer Product "Listed" Product: Terramycin® Soluble Powder, NADA 008-622

**2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an

ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily the ANADA sponsor shows that the generic product is bioequivalent to the pioneer and conducts a tissue residue study to establish the withdrawal time for the generic product. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (61 FR 26182, May 24, 1996, Bioequivalency Guideline).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for OXYTETRACYCLINE HCL SOLUBLE POWDER-343. The generic and pioneer products are water soluble powders with the same active ingredients and no differences in the inactive ingredients which would affect absorption of the active ingredients.

### 3. HUMAN FOOD SAFETY

#### Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for the sum of residues in tissues of cattle, beef calves, dairy calves, swine, chickens, turkeys as follows:

- (a) 2 ppm in muscle
- (b) 6 ppm in liver
- (c) 12 ppm in fat and kidney

#### Withdrawal Time:

On April 18, 1997, a waiver from the requirement of an *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

For oxytetracycline hydrochloride, [21 CFR 520.1660d], do not administer to turkeys, swine, cattle, or sheep within 5 days of slaughter. Do not administer to chickens or turkeys producing eggs for human consumption.

#### Regulatory Method:

The analytical method for the determination of oxytetracycline hydrochloride in tissues uses a microbiological assay procedure. This method is found in the Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols, revised October 1968, reprinted December 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

#### 4. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Oxytetracycline HCl Soluble Powder-343, when used under its proposed conditions of use, is safe and effective for the labeled indications.

**Attachments:** The following **generic** labeling and currently approved **pioneer** labeling are attached.

Generic Labeling

1. Facsimile package labeling for generic product

Pioneer Labeling

2. Pioneer package labeling for Terramycin<sup>®</sup> Soluble Powder

**CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys or 5 consecutive days in cattle, swine or sheep. Prepare fresh solutions every 24 hours.  
**Special Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate and the environmental temperature and humidity, each of which affects water consumption.

**WARNING:** Do not administer to turkeys, swine, cattle or sheep within 5 days of slaughter. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding for this product. In pre-ruminating calves, Do not use in calves to be processed for veal. A withdrawal period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

RECOMMENDED STORAGE: STORE BELOW 77°F (25°C)

FOR USE IN DRINKING WATER ONLY  
 NOT FOR USE IN LIQUID FEED SUPPLEMENTS  
 FOR ANIMAL USE ONLY  
 KEEP OUT OF REACH OF CHILDREN  
 Restricted Drug(s) (California),  
 Not For Human Use,  
 Use Only As Directed.



Iss. 5-98

800507  
 Manufactured By:  
 Phoenix Scientific, Inc.  
 St. Joseph, MO 64506

Lot No. \_\_\_\_\_ Exp. Date \_\_\_\_\_

NDC 59130-704-08

# OXYTETRACYCLINE HCl SOLUBLE POWDER-343

A broad spectrum  
**ANTIBIOTIC**

For control and treatment of specific diseases in poultry,  
 cattle, sheep and swine.

This bucket contains 686 grams of  
 oxytetracycline HCl

For oral use only.

**NET WEIGHT: 907.2 g (2 Lb)**

ANADA 200-247, APPROVED BY FDA



**INDICATIONS AND DIRECTIONS FOR USE**  
 For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline: Add the following amount to two gallons of stock solution when proportioned as set to meter at the rate of one ounce per gallon. The enclosed measuring cup holds 68 g (2.4 oz) of product when leveled at the 80 ml mark.

DISEASE	DOSAGE	SCOOPS/2 GALLONS STOCK SOLUTION
<b>CHICKENS</b>		
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	200-400 mg/gal	1-2
Chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	400-800 mg/gal	2-4
Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg/gal	2-4
<b>TURKEYS</b>		
Hexamitiasis caused by <i>Hexamita meleagridis</i>	200-400 mg/gal	1-2
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	400 mg/gal	2
Growing Turkeys—Complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis)	25 mg/lb body weight daily	varies with age & water consumption (1 pound wild trout 13,720 pounds of turkeys.)

Medicate continuously at the first clinical signs of disease and continue for 7 to 14 consecutive days. If improvement is not noted within 24-48 hours, consult a poultry diagnostic laboratory or poultry pathologist to determine diagnosis and advice on dosage.

For the control and treatment of the following diseases caused by organisms susceptible to oxytetracycline.

DISEASE	DOSAGE
<b>SWINE</b>	
Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
Bacterial pneumonia caused by <i>Pasteurella multocida</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
For Breeding Swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> .	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
<b>CATTLE, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE</b>	
Bacterial enteritis caused by <i>Escherichia coli</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
Bacterial pneumonia (shipping fever complex) caused by <i>Pasteurella multocida</i> .	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
<b>SHEEP</b>	
Bacterial enteritis caused by <i>Escherichia coli</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
Bacterial pneumonia (shipping fever complex) caused by <i>Pasteurella multocida</i> .	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

This bucket will treat 68,600 pounds of swine, cattle or sheep at 10 mg/pound.

## CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC  
 P.O. #: PROOF Date Sent: 9/17/97 9/23/97+ 5/6/98

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Approved by: \_\_\_\_\_  
 Date approved: \_\_\_\_\_

QC 5/10/98  
 let 5/11/98  
 5-11-98

**CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys or 5 consecutive days in cattle, swine or sheep. Prepare fresh solutions every 24 hours.  
**Special Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate and the environmental temperature and humidity, each of which affects water consumption.

**WARNING:** Do not administer to turkeys, swine, cattle or sheep within 5 days of slaughter. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

RECOMMENDED STORAGE: STORE BELOW 77°F (25°C)

FOR USE IN DRINKING WATER ONLY  
 NOT FOR USE IN LIQUID FEED SUPPLEMENTS  
 FOR ANIMAL USE ONLY  
 KEEP OUT OF REACH OF CHILDREN  
 Restricted Drug(s) (California),  
 Not For Human Use,  
 Use Only As Directed.

TAKE TIME



OBSERVE LABEL DIRECTIONS

Iss. 5-98

800507  
 Manufactured By:  
 Phoenix Scientific, Inc.  
 St. Joseph, MO 64506

Lot No.

Exp. Date

NDC 59130-704-09

# OXYTETRACYCLINE HCl SOLUBLE POWDER-343

A broad spectrum  
 ANTIBIOTIC

For control and treatment of specific diseases in poultry,  
 cattle, sheep and swine.

This bucket contains 1,715 grams of  
 oxytetracycline HCl

For oral use only.

NET WEIGHT: 2.26 kg (5 Lb)

ANADA 200-247, APPROVED BY FDA

**AmTech**<sup>®</sup>  
 Group, Inc.

**INDICATIONS AND DIRECTIONS FOR USE**  
 For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline. Add the following amount to two gallons of stock solution when proportioner is set to meter at the rate of one ounce per gallon. The enclosed measuring cup holds 88 g (2.4 oz) of product when leveled at the 80 mL mark.

CHICKENS	DOSAGE	SCOOPS/2 GALLONS STOCK SOLUTION
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	200-400 mg/gal	1-2
Chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	400-800 mg/gal	2-4
Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg/gal	2-4
TURKEYS		
Hexamitiasis caused by <i>Hexamita meleagridis</i>	200-400 mg/gal	1-2
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	400 mg/gal	2
Growing Turkeys-Complicating bacterial organisms associated with bluecomb (transmissible enteritis)	25 mg/lb body weight daily	varies with age & water consumption (1 pound will treat 12,220 pounds of turkeys.)

Medicate continuously at the first clinical signs of disease and continue for 7 to 14 consecutive days. If improvement is not noted within 24-48 hours, consult a poultry diagnostic laboratory or poultry pathologist to determine diagnosis and advice on dosage.

For the control and treatment of the following diseases caused by organisms susceptible to oxytetracycline.

SWINE	DOSAGE
Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
Bacterial pneumonia caused by <i>Pasteurella multocida</i>	
For Breeding Swine: Leptospirosis (producing the disease by <i>Leptospira pomona</i> )	
CATTLE, BEEF CATTLE AND NON-LACTATING DAIRY	
Bacterial enteritis caused by <i>Escherichia coli</i>	
Bacterial pneumonia (shipping fever complex) caused by <i>Pasteurella multocida</i> .	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.
SHEEP	
Bacterial enteritis caused by <i>Escherichia coli</i>	
Bacterial pneumonia (shipping fever complex) caused by <i>Pasteurella multocida</i> .	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

This bucket will treat 171,500 pounds of swine, cattle or sheep at 10 mg/pound.

## CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC

P.O. #: PROOF Date Sent: 9/17/97 9/23/97 5/6/98

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Approved by: \_\_\_\_\_

Date approved: \_\_\_\_\_

Handwritten notes:  
 12/10/98  
 12/11/98  
 PG 5-11-98

CUSTOMER PROOF • CHECK CAREFULLY!

Customer: 23444 (sh) Phoenix Scientific  
P.O. #: proof Date: 10/2/97 Sent: 10/2/97

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

LS 10/98  
05/11/98  
05-1-96

### INDICATIONS AND DIRECTIONS FOR USE

For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline: Add the following amount to two gallons of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

CHICKENS	DOSAGE	PACKS/2 GALLONS STOCK SOLUTION
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	200-400 mg/gal	1/4 - 1/2
Chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	400-800 mg/gal	1/2 - 1
Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg/gal	1/2 - 1
TURKEYS		
Hexamitiasis caused by <i>Hexamita meleagridis</i>	200-400 mg/gal	1/4 - 1/2
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	400 mg/gal	1/2
Growing Turkeys-Complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)	25 mg/lb body weight daily	varies with age & water consumption (1 packet will treat 8192 pounds of turkeys.)

Medicate continuously at the first clinical signs of disease and continue for 7 to 14 consecutive days. If improvement is not noted within 24-48 hours, consult a poultry diagnostic laboratory or poultry pathologist to determine diagnosis and advice on dosage.

For the control and treatment of the following diseases caused by organisms susceptible to oxytetracycline.

SWINE	DOSAGE
Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily.
Bacterial pneumonia caused by <i>Pasteurella multocida</i>	Administer up to 5 days
For Breeding Swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> .	
CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE	
Bacterial enteritis caused by <i>Escherichia coli</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily.
Bacterial pneumonia (shipping fever complex) caused by <i>Pasteurella multocida</i> .	Administer up to 5 days.
SHEEP	
Bacterial enteritis caused by <i>Escherichia coli</i>	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily.
Bacterial pneumonia (shipping fever complex) caused by <i>Pasteurella multocida</i> .	Administer up to 5 days.

This packet will treat 20,480 pounds of swine, cattle or sheep at 10 mg/pound.

**CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys or 5 consecutive days in cattle, swine or sheep. Prepare fresh solutions every 24 hours.

**Special Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate and the environmental temperature and humidity, each of which affects water consumption.

**WARNING:** Do not administer to turkeys, swine, cattle or sheep within 5 days of slaughter. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. A withdrawal period has not been established for this product in prerinulating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

**RECOMMENDED STORAGE:** STORE BELOW 77°F (25°C)

**FOR USE IN DRINKING WATER ONLY NOT FOR USE IN LIQUID FEED SUPPLEMENTS**

Restricted Drug(s) (California), Not For Human Use, Use Only As Directed.

Lot No.

Exp. Date

800507

TAKE TIME



OBSERVE LABEL DIRECTIONS

Manufactured By:  
Phoenix Scientific, Inc.  
St. Joseph, MO 64506

Iss. 5-98

NDC 59130-704-27

# OXYTETRACYCLINE HCl SOLUBLE POWDER-343

## A broad spectrum ANTIBIOTIC

For control and treatment of specific diseases in poultry, cattle, sheep and swine.

This packet contains 204.8 grams of oxytetracycline HCl.

This packet will make:

1,024 gallons (3,876 L) containing 200 mg oxytetracycline HCl per gallon  
512 gallons (1,938 L) containing 400 mg oxytetracycline HCl per gallon  
256 gallons (969 L) containing 800 mg oxytetracycline HCl per gallon

For oral use only.

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

NET WEIGHT: 272.2 g (9.6 oz)

ANADA 200-247 APPROVED BY FDA

AmTech®  
Group, Inc.

2

**INDICATIONS AND DIRECTIONS FOR USE**

For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline: Add the following amount to two gallons of stock solution when proportion is set to that of the rate of one ounce per gallon.

	DOSAGE	PACKS/2 GALLONS STOCK SOLUTION
<b>CHICKENS</b> Irritation caused by <i>Mycoplasma synoviae</i>	200-400 mg/pt of	5 - 10
Chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	400-800 mg/pt of	10 - 20
Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg/pt of	10 - 20
<b>TURKEYS</b> Hemorrhages caused by <i>Haemophilus meleagridis</i>	200-400 mg/pt of	5 - 10
Irritation caused by <i>Mycoplasma synoviae</i>	400 mg/pt of	10
Growing Turkeys Complicating bacterial or myxoma associated with bluecomb (transmissible arthritis, coronavirus arthritis)	25 mg/lb body weight daily	venous with age & water consumption (1 packet will treat 400 pounds of turkeys.)

Medicate continuously at the first clinical signs of disease and continue for 7 to 14 consecutive days. If improvement is not noted within 24-48 hours, consult a poultry diagnostic laboratory or poultry pathologist to determine diagnosis and advice on dosage.

For the control and treatment of the following diseases caused by organisms susceptible to oxytetracycline:

**SWINE**  
Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*  
Bacterial pneumonia caused by *Pasteurella multocida*  
For Breeding Swine: Leptospirosis (reducing the incidence of abortion and shedding of leptospira) caused by *Leptospira pomona*.

**CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE**  
Bacterial enteritis caused by *Escherichia coli*  
Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.

**SHEEP**  
Bacterial enteritis caused by *Escherichia coli*  
Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.

**DOSAGE**  
Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily.  
Administer up to 14 days.

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily.  
Administer up to 14 days.

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily.  
Administer up to 14 days.

This packet will treat 1000 pounds of swine, cattle or sheep at 10 mg/pound.



**Pfizer**

TO OPEN CARTON

# Terramycin®

(oxytetracycline HCl)

## Soluble Powder

4166

A broad-spectrum  
**antibiotic**  
for control and treatment of specific  
diseases in poultry, cattle, swine  
and sheep.

This packet contains 10 grams  
of oxytetracycline HCl.

FOR ORAL USE ONLY

NADA #81622 APPROVED BY FDA

Net Weight: 6.4 oz (181.4 g)

**CAUTION:** Use as sole source of oxytetracycline. Prepare fresh solutions every 24 hours.  
**Special Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate and the environmental temperature and humidity, each of which affects water consumption.

**WARNING**  
Do not administer to turkeys, swine, cattle or sheep within 5 days of slaughter. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers.

Refer to package insert for complete directions.  
**RECOMMENDED STORAGE: STORE BELOW 77°F (25°C)**  
**FOR USE IN DRINKING WATER ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS**  
Restricted Drug(s) (California), Not For Human Use, Use Only As Directed.  
**FOR ANIMAL USE ONLY**  
**KEEP OUT OF REACH OF CHILDREN**

Distributed by  
**Pfizer Animal Health**  
New York, New York, USA

01-2358-35-0  
MADE IN USA

