

TETRA-BAC 324- tetracycline hydrochloride powder, for solution
Huvepharma, Inc

TETRA-BAC 324

Front Panel

NDC 23243-300-09

TETRA-BAC® 324

(tetracycline hydrochloride)

Soluble Powder

Antibiotic

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Each pound contains 324g of tetracycline hydrochloride.

FOR USE IN ANIMALS ONLY

KEEP OUT OF REACH OF CHILDREN

Restricted Drug (California)-Use Only as Directed

Approved by FDA under ANADA # 200-049

NET WEIGHT:

5 lb (2.27g)

INDICATIONS: For use in the control and treatment of the following conditions in swine, calves and poultry.

SWINE AND CALVES: Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Actinobacillus pleuropneumoniae*, *Pasteurella* spp., *Klebsiella* spp. susceptible to tetracycline.

RECOMMENDED DOSAGE LEVEL: Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to provide 10 mg/lb of body weight per day in divided doses.

RESIDUE WARNING: SWINE- Do not slaughter animals for food purposes within 4 days of treatment. **CALVES-** Do not slaughter animals for food purposes within 5 days of treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

CAUTION: Do not use for more than 5 consecutive days.

DIRECTIONS FOR USE: Administer for 3-5 days.

CHICKENS: Control of chronic respiratory disease (CRD) and air sac disease caused by *Mycoplasma gallisepticum* and *Escherichia coli*; infectious synovitis caused by *Mycoplasma synoviae* sensitive to tetracycline hydrochloride.

RECOMMENDED DOSAGE LEVEL: CRD and air sac disease: Use soluble powder in the drinking water at a drug level of 400-800 mg tetracycline hydrochloride per gallon. Infectious synovitis: Use soluble powder in the drinking water at a drug level of 200-400 mg tetracycline hydrochloride per gallon.

TURKEYS: Control of infectious synovitis caused by *Mycoplasma synoviae*; bluecomb (transmissible enteritis, coronaviral enteritis) complicated by organisms susceptible to tetracycline hydrochloride.

RECOMMENDED DOSAGE LEVEL: Infectious synovitis; 400 mg tetracycline hydrochloride per gallon of drinking water. Bluecomb; 25 mg/lb body weight of tetracycline hydrochloride per day in divided doses.

RESIDUE WARNING: Do not slaughter birds for food within 4 days of treatment.

CAUTION: Not for use in turkeys or chickens producing eggs for human consumption. Do not use for more than 14 consecutive days.

DIRECTIONS FOR USE: Administer for 7-14 days. Medicate at first clinical signs of disease or when experience indicates the disease may be the problem.

GENERAL CAUTION: Prepare fresh solutions at least once a day. Solutions are not stable for more than 24 hours. Use as a sole source of tetracycline. Diagnosis should be reconsidered if improvement is not noticed within 3 days. The concentration of drug required in medicated water must be adequate to compensate for variations in the age and class of animals; feed consumption, and environmental temperature and humidity, each of which affects water consumption.

Manufactured for

Huvepharma, Inc.
525 Westpark Dr., Suite 230
Peachtree City, GA 30269

® Registered trademark of Huvepharma, Inc.

MIXING DIRECTIONS:

FOR SWINE, CALVES AND TURKEYS: Add one level scoop (1.26 oz) to 250 mL (8.5 oz) of

warm water and dissolve. This will provide stock solution of 100 mg/mL of tetracycline hydrochloride. **FOR TURKEYS ONLY:** This stock solution when metered at approximately

1 oz per gallon, will provide drinking water containing 2,957 mg of tetracycline hydrochloride activity per gallon.

The contents of the enclosed scoop are sufficient to deliver the recommended daily dosage levels as follows:

At 25 mg/lb of body weight 1,020 total lbs of turkey to be medicated

At 10 mg/lb of body weight 2,550 total lbs of swine or calves to be medicated

Individual calf treatment 5 mL (1 measuring teaspoon) twice daily for each 100 lbs

of body weight administered as a drench or by dose syringe

CHICKENS AND TURKEYS: To arrive at the recommended dosages, prepare stock solutions as follows and meter into the drinking water at 1 oz per gallon.

200 mg/gallon - dissolve 1 level scoop (1.26 oz) in 3,785 mL warm water (1 gallon)-
Provides 128 gallons medicated drinking water.

400 mg/gallon - dissolve 1 level scoop (1.26 oz) in 1,892 mL warm water (0.5 gallon)-
Provides 64 gallons medicated drinking water.

800 mg/gallon - dissolve 1 level scoop (1.26 oz) in 946 mL warm water (0.25 gallon)-
Provides 32 gallons medicated drinking water.

SPECIAL DIRECTIONS FOR BABY CALVES AND BABY PIGS: Administer this product one

hour before or two hours after feeding milk or milk replacers. Provide clean (unmedicated)

drinking water at all times. **NOTE:** When using a watering trough, this product is to be administered twice a day in the drinking water of swine, calves and poultry. One-half of the

recommended daily dosage level of antibiotic is to be consumed during each administration

period, thus providing the drug in divided doses.

The contents of this container (5 lb) will provide sufficient drug to treat 162,000 total pounds of swine or calves for a single day at the recommended dosage level of 10 mg/lb of body weight in divided doses. Or the contents of this container will treat 64,800 lbs of turkeys when supplied at 25 mg/lb or at 200-800 mg/gallon will provide 2,025 to 8,100 gallons of medicated drinking water for chickens or turkeys.

To report suspected adverse drug events, for technical assistance or to obtain a copy of

the Safety Data Sheet, contact Huvepharma, Inc., at 1-877-426-7765 or www.huvepharma.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

Store between 59-86°F (15-30°C)

T-3897-09

Rev. 02-2021

Take Time

Take Time



Observe Label
Directions

LOT NO.: EXP. DATE:

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RESIDUE WARNING: SWINE - Do not slaughter animals for food purposes within 4 days of treatment. **CALVES** - Do not slaughter animals for food purposes within 5 days of treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

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DIRECTIONS FOR USE: Administer for 3-5 days.

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TURKEYS: Control of infectious synovitis caused by *Mycoplasma synoviae*; bluecomb (transmissible enteritis, coronavirus enteritis) complicated by organisms susceptible to tetracycline hydrochloride.

RECOMMENDED DOSAGE LEVEL: Infectious synovitis; 400 mg tetracycline hydrochloride per gallon of drinking water. Bluecomb; 25 mg/lb body weight of tetracycline hydrochloride per day in divided doses.

RESIDUE WARNING: Do not slaughter birds for food within 4 days of treatment.

CAUTION: Not for use in turkeys or chickens producing eggs for human consumption. Do not use for more than 14 consecutive days.

DIRECTIONS FOR USE: Administer for 7-14 days. Medicate at first clinical signs of disease or when experience indicates the disease may be the problem.

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At 25 mg/lb of body weight	1,020 total lbs of turkey to be medicated
At 10 mg/lb of body weight	2,550 total lbs of swine or calves to be medicated
Individual calf treatment	5 mL (1 measuring teaspoonful) twice daily for each 100 lbs of body weight administered as a drench or by dose syringe

CHICKENS AND TURKEYS: To arrive at the recommended dosages, prepare stock solutions as follows and meter into the drinking water at 1 oz per gallon.

200 mg/gallon - dissolve 1 level scoop (1.26 oz) in 3,785 mL warm water (1 gallon) - Provides 120 gallons medicated drinking water.
400 mg/gallon - dissolve 1 level scoop (1.26 oz) in 1,890 mL warm water (0.5 gallon) - Provides 64 gallons medicated drinking water.
800 mg/gallon - dissolve 1 level scoop (1.26 oz) in 945 mL warm water (0.25 gallon) - Provides 32 gallons medicated drinking water.

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Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:23243-3000
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACYCLINE HYDROCHLORIDE (UNII: P6R62377KV) (TETRACYCLINE - UNII:F8VB5M810T)	TETRACYCLINE HYDROCHLORIDE	324 g in 453.6 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-3000-9	2268.0 g in 1 PAIL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200049	02/19/2021	

Labeler - Huvepharma, Inc (619153559)