TETRASOL- tetracycline hydrochloride powder, for solution Med-Pharmex, Inc

TETRASOL SOLUBLE POWDER

(tetracycline hydrochloride)

Antibiotic

Approved by FDA under ANADA # 200-234

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

FOR USE IN ANIMALS ONLY - - KEEP OUT OF REACH OF CHILDREN

Each pound contains 324 g of tetracycline hydrochloride. Net Wt.: 5 lbs. (2.27 kg)

INDICATIONS FOR USE:

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

SWINE AND CALVES

INDICATIONS: Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli*; bacterial pneumonia associated with *Actinobacillus pleuropneumoniae*, *Pasteurella* spp. and *Klebsiella* spp. sensitive to tetracycline hydrochloride.

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.

CAUTION: Do not use for more than 5 consecutive days. **DIRECTIONS FOR USE:** Administer for 3-5 days.

CHICKENS

INDICATIONS: 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

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

RECOMMENDED DOSAGE LEVEL: Infectious synovitis: Use soluble powder in the drinking water at a drug level of 400 mg tetracycline hydrochloride per gallon. Bluecomb: Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to provide 25 mg/lb of body weight per day in divided doses.

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 sign of disease or when experience indicates the disease may be a problem.

WARNINGS:

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.

POULTRY - Do not slaughter birds for food within 4 days of treatment.

GENERAL CAUTION:

Prepare fresh solutions at least once a day. Solutions are not stable for more than 24 hours. Use as 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.

DOSAGE AND ADMINISTRATION:

MIXING DIRECTIONS

FOR SWINE, CALVES AND TURKEYS: 2.52 oz. (two scoops) dissolved in 500 mL (approximately 17 fl. oz.) of warm water will provide a stock solution of 100 mg of tetracycline hydrochloride activity per mL.

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 two scoops are sufficient to deliver the recommended daily dosage levels as follows: At 25 mg/lb of body weight 2,040 total lbs of turkeys to be medicated.

At 10 mg/lb of body weight 5,100 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.

FOR CHICKENS AND TURKEYS: To arrive at the recommended dosages, use the enclosed contents of 2 scoops to prepare stock solutions as follows:

200 mg/gallon - dissolve 2 scoops (2.52 oz.) in 7,570 mL warm water (2 gallons)

400 mg/gallon - dissolve 2 scoops (2.52 oz.) in 3,785 mL warm water (1 gallon)

800 mg/gallon - dissolve 2 scoops (2.52 oz.) in 1,892 mL warm water (0.5 gallon)

These stock solutions should then be metered into drinking water at approximately 1 oz. per gallon.

At 200-800 mg/gallon two scoops will provide 63.8 to 255 gallons of medicated drinking water.

SPECIAL DIRECTIONS FOR BABY CALVES AND BABY PIGS - Net Weight: 5 lbs. (2.27 kg)

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 lbs) 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.

RESTRICTED DRUG (California) - USE ONLY AS DIRECTED

TAKE TIME OBSERVE LABEL DIRECTIONS

CONTACT INFORMATION:

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Med-Pharmex at (800) 587-4306. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae

Manufactured by:

Med-Pharmex, Inc. Pomona, CA 91767

Rev. Feb. 2024

TETRASOL
tetracycline hydrochloride powder, for solution

Product Information									
Product Type	PRESCRIPTION ANIMAL DRUG		Item Code (Source)		NDC:54925-033				
Route of Administration	ORAL								
Active Ingredient/Active Moiety									
Ingredient Name				Basis of Strength			Strength		
TETRACYCLINE HYDROCHLORIDE (UNII: P6R62377KV) (TETRACYCLINE - UNII:F8VB5M810T)				TETRACYCLINE HYDROCHLORIDE 714 g			714 g in 1 kg		
Packaging									
# Item Code Packa	ge Description	Marketin	g Start 🛛	Date	Marketing End Date				
1 NDC:54925-033-50 2.27 kg in 1 C	ONTAINER								
Marketing Information									
Marketing Category Applicati	Application Number or Monograph Citation			Marketing Start Date			Marketing End Date		
ANADA ANADA200234			07/22/1997						

Labeler - Med-Pharmex, Inc (025353699)

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Med-Pharmex, Inc