PENNOX 100 HI-FLO- oxytetracycline powder Pharmgate Animal Health

Pennox 100 Hi-Flo®

Oxytetracyline
Type A Medicated Article

Active Drug Ingredients: Oxytetracycline (from oxytetracycline dihydrate base) equivalent to 100 grams Oxytetracycline Hydrochloride/lb.

Ingredients: Oxytetracycline, Calcium Carbonate, Roughage Products and Mineral Oil.

For Use in the Manufacture of Medicated Feeds. Do Not Feed Undiluted.

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

SUPPLEMENTS

Directions For Use

by Mycoplasma synoviae susceptible to

oxytetracycline (Feed continuously for 7 - 14 days)

INDICATIONS FOR USE	Use Level of Oxytetracycline	lbs. of Pennox 100 Hi-Flo® per ton
Chickens		
For Chickens: Control of infectious synovitis caused by <i>Mycoplasma synoviae,</i> control of fowl cholera caused by <i>Pasteurella multocida</i> sensitive to oxytetracycline. (Feed continuously for 7 - 14 days)	100-200 g/ton	1.0 - 2.0
For Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by Mycoplasma gallisepticum and Escherichia coli susceptible to oxytetracycline. (Feed continuously for 7 - 14 days).	400 g/ton	4.0
For Broiler Chickens: Reduction of mortality due to air sacculitis (air sac infection) caused by <i>Escherichia coli</i> susceptible to oxytetracycline (Feed continuously for 5 days).	500 g/ton	5.0
Withdrawal Periods and Residue Warnings: Do	not feed to chicke	ens producing
eggs for human consumption. Do not use in low cale 0.55% dietary calcium. Use in such feeds may result withdrawal period at 500 g/ton use levels. No withdraccording to labeling at 100 – 200 g/ton and 400 g/to	in violative residue awal period is requ	es. 24 hour
Turkeys		
For Turkeys: Control of hexamitiasis caused by Hexamita meleagridis susceptible to oxytetracycline. (Feed continuously for 7 - 14 days). For Turkeys: Control of infectious synovitis caused	•	1.0

200g/ton

2.0

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

25 mg/lb. body weight/day

Withdrawal Periods and Residue Warnings: Do not feed to turkeys producing eggs for human consumption. Zero-day withdrawal period.

Swine

For Swine: Treatment of bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* consumption to provide 10 mg/lb. susceptible to oxytetracycline. (Feed continuously for 7-14 days.)

Feed approximately 400 g/t, varying with body weight and feed body weight/ day

For Breeding Swine: Control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by Leptospira pomona susceptible to oxytetracycline. (Feed continuously for 14 days)

Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb. body weight/ day

Withdrawal Periods: Zero-day withdrawal period.

Calves, Beef Cattle, and Nonlactating Dairy Cattle

For Growing cattle (over 400 lbs.): For the reduction of the incidence of liver abscesses. (Use continuously)

75 mg/head/day

For Cattle: For the prevention and treatment of the early stages of the shipping fever complex. (Feed 3-5 days before and after arrival in feedlots.)

0.5-2.0g/head/day

For Calves, Beef Cattle, and Nonlactating

Dairy Cattle: Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by Pasteurella multocida susceptible to oxytetracycline. (Feed continuously for 7-14 days)

10 mg/lb. body weight/day

Withdrawal Periods and Residue Warnings: This drug product is not approved for use in female cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residue in milk and/or in calves born to these cows. 5-day withdrawal period at 10 mg/lb. body weight/day use level. No withdrawal period is required when used according to labeling at 75 mg/head/day and 0.5-2.0g/head/day use levels.

Sheep

For Sheep: Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by Pasteurella multocida susceptible to oxytetracycline. (Feed continuously for 7-14 days)

Withdrawal Periods: 5-day withdrawal period.

10 mg/lb. body weight/day

Honey Bees

Control of American Foulbrood caused by Paenibacillus larvae and European Foulbrood caused

200 mg/oz (Dusting) 200 ma/E lh /Cvrun)

200 mg/patty (Extender Patty)

See Mixing, Preparation and Feeding Directions below.

Mixing Directions for Honey Bees

To manufacture a Type B medicated feed containing 20g/lb of oxytetracycline hydrochloride activity, mix 5 lb of Pennox 100 Hi-Flo with 20 lb of powdered sugar (for a total of 25 lb.) To manufacture a Type C medicated feed containing 200 mg of oxytetracycline hydrochloride activity per oz (dusting Type C medicated feed), mix 7 lb of Pennox 100 Hi-Flo with 211 lb of powdered sugar (for a total of 218 lb). The resulting Type C medicated feed is fed as-is for dusting, or is used to prepare syrup and extender patty feeds.

Feeding Directions for Dusting:

Dusting: Apply 1 oz (200 mg oxytetracycline) of dusting Type C medicated feed per colony every 4 to 5 days for a total of 3 applications. Apply the dust on the outer parts or ends of the frames.

Caution: Dusting of uncapped brood cells has been reported to cause death of larval honey bees. Do not dust uncapped brood cells.

Preparation and Feeding Directions for Syrup:

Preparation: First dissolve 1 oz (200 mg oxytetracycline) of the dusting Type C medicated feed in a small quantity of water, then mix into 5 lb of 1:1 sugar syrup (equal parts sugar and water, w/w).

Feeding: Feed 5 lb of syrup (200 mg oxytetracycline) per colony every 4 to 5 days for a total of 3 applications. Bulk feed the syrup using feeder pails, or division board feeders, or by filling the combs. Prepare fresh syrup for each application.

Preparation and Feeding Directions for Extender Patty:

Preparation: Make one patty by mixing 4 oz (800 mg oxytetracycline) of the dusting Type C medicated feed with 5.8 oz (165 g) of vegetable shortening and 11.6 oz (330 g) of sugar.

Feeding: Place one patty per colony on the top bars of the brood nest frames in a single application.

Warnings:

Withdrawal Periods and Residue Warnings: Remove at least 6 weeks prior to main honey flow. Type C medicated feeds should be fed in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Honey stored during medication periods in combs for surplus honey should be removed following final mediation of the bee colony and must not be used for human food. Waring: Do not use in a manner contrary to state apiary laws and regulations. Each state has specific regulations relative to disease control and medication. Contact the appropriate official or state departments of agriculture for specific inter- and intrastate laws and regulations.

Approved by FDA under NADA # 138-938

Pennox 100 Hi-Flo® is the registered trademark of Pharmgate Inc.

Marketed by:

Pharmgate Animal Health, LLC 14040 Industrial Road Omaha, NE 68144



PRINCIPAL DISPLAY PANEL - 22.68 Kg Bag

Pennox 100 Hi-Flo®

Oxytetracycline Type A Medicated Article

CAUTION: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

See mixing directions, claims, cautions and warnings on back. Restricted Drug (California) - Use Only as Directed. Not For Human Use.

Net wt. 50 LB (22.68 Kg)

Pharmgate ANIMAL HEALTH



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Product Type

VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG

NDC:51429-103

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Oxytetracycline (UNII: X20I9EN955) (Oxytetracycline Anhydrous - UNII:SLF0D9077S)	Oxytetracycline	220 g in 1 kg

Inactive Ingredients			
Ingredient Name	Strength		
Calcium Carbonate (UNII: H0G9379FGK)			
Mineral Oil (UNII: T5L8T28FGP)			

ı	Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:51429-103-02	22.68 kg in 1 BAG				

Marketing I	larketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA138938	12/23/2008		

Labeler - Pharmgate Animal Health (833270817)

Registrant - Pharmgate Inc. (079628671)

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