LINXMED-SP- lincomycin hydrochloride powder Bimeda, Inc.

LinxMed-SP®

(lincomycin hydrochloride) Soluble Powder

Antibacterial

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

FOR ORAL USE IN SWINE, HONEY BEES, AND BROILER CHICKENS ONLY. Not for use in layer and breeder chickens.

The 40 g packet contains as active ingredient: Lincomycin hydrochloride equivalent to lincomycin......16 g

The 80 g packet contains as active ingredient: Lincomycin hydrochloride equivalent to lincomycin......32 g

The 480 g packet contains as active ingredient: Lincomycin hydrochloride equivalent to lincomycin......192 g

Each gram of powder in the 2 lb container contains as active ingredient: Lincomycin hydrochloride equivalent to lincomycin......400 mg

Approved by FDA under ANADA # 200-377

SWINE: Directions for Use

INDICATIONS AND USAGE: LinxMed-SP Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

DOSAGE AND ADMINISTRATION

Dosage: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

Treatment Period: The drug should be administered for a minimum of 5 consecutive days beyond disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

Administration:

The 40 g packet will medicate 64 gallons of drinking water providing 250 mg/gallon. The 80 g packet will medicate 128 gallons of drinking water providing 250 mg/gallon. The 160 g packet will medicate 256 gallons of drinking water providing 250 mg/gallon. The 480 g packet will medicate 768 gallons of drinking water providing 250 mg/gallon. One scoop (provided) of powder from the 2 lb container will medicate 64 gallons of drinking water providing 250 mg/gallon.

A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these

circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption.

For use in automatic water proportioners, prepare the stock solution by dissolving the amount of powder indicated (in packets or scoops) below into the number of gallons of water indicated; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

	Amount of powder	# Gallon(s) of Water		
40 g packet	2 packets	1		
80 g packet	1 packet	1		
160 g packet	1 packet	2		
480 g packet	1 packet	6		
2 lb	2 scoops	1		

NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

HONEY BEES: Directions for Use

INDICATIONS AND USAGE: LinxMed-SP Soluble Powder is indicated for the control of American foulbrood (Paenibacillus larvae) in honey bees.

DOSAGE AND ADMINISTRATION

Dosage: Administer 100 mg lincomycin per hive

Treatment Period: The drug should be administered to the hive weekly for 3 weeks.

Administration: Mix 250 mg LinxMed-SP Soluble Powder (100 mg lincomycin) with 20 g confectioners'/powdered sugar and dust over the tops of the brood chamber.

BROILER CHICKENS: Directions for Use

INDICATIONS AND USAGE: LinxMed-SP Soluble Powder is indicated for the control of necrotic enteritis caused by Clostridium perfringens susceptible to lincomycin.

DOSAGE AND ADMINISTRATION

Dosage: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

Treatment Period: Start medication as soon as the diagnosis of necrotic enteritis is determined. The drug should be administered for 7 consecutive days.

Administration:

The 40 g packet will medicate 250 gallons of drinking water providing 64 mg/gallon. The 80 g packet will medicate 500 gallons of drinking water providing 64 mg/gallon. The 160 g packet will medicate 1,000 gallons of drinking water providing 64 mg/gallon. The 480 g packet will medicate 3,000 gallons of drinking water providing 64 mg/gallon. One scoop (provided) of powder from the 2 lb container will medicate 250 gallons of drinking water providing 64 mg/gallon.

NOTE: After water medication is discontinued, a recommended control program for necrotic enteritis consists of feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

PRECAUTIONS

Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. Do not use the water treatment and the feed treatments simultaneously. Do not allow rabbits, hamsters, guinea pigs, horses or ruminants access to water containing lincomycin treatment. Ingestion by these species may result in severe gastrointestinal effects.

Swine: If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended

Chickens: Not for use in layer and breeder chickens.

WARNING: Not for human use.

RESIDUE WARNINGS:

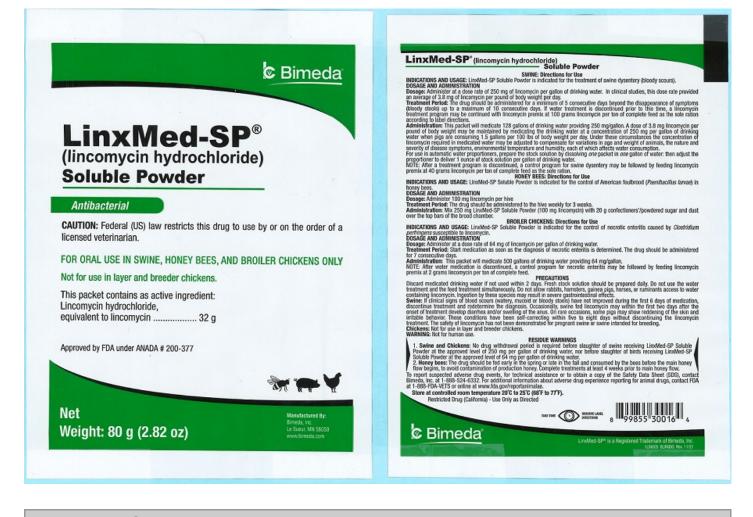
1. Swine and Chickens: No drug withdrawal period is required before slaughter of swine receiving LinxMed-SP Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LinxMed-SP Soluble Powder at the approved level of 64 mg per gallon of drinking water.

2. Honey bees: The drug should be fed early in the sprint or late in the fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks prior to main honey flow.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

Store at controlled room temperature 20°C to 25°C (68°F to 77°F).

Restricted Drug (California) - Use Only as Directed



LIN	IXMED-SP							
linco	omycin hydrochlo	oride pow	der					
Pr	oduct Informa	tion						
Product Type PRESCRIPTION ANIMAL DR		AL DRUG	ltem Code (Source)		NDC:61133-5482			
Ro	ute of Administra	ation	ORAL					
Active Ingredient/Active Moiety								
Ingredient Name					Basis of Strength		Strength	
Lincomycin Hydrochloride (UNII: M6T05Z2B68) (Lincomycin - UNII:BOD072YW0F)				Lincomycin 32 g		32 g in 80 g		
Ра	ckaging							
#	ltem Code	Packa	ge Description	Marketi	ng Start D	ate Marke	eting	End Date
1 N	IDC·61133-5482-2	80 a in 1	РОИСН					

80 g

1	NDC:61133-5482-2	80 g in 1 POUCH	
2	NDC:61133-5482-1	40 g in 1 POUCH	
3	NDC:61133-5482-3	907.18 g in 1 POUCH	
4	NDC:61133-5482-4	480 g in 1 POUCH	
5	NDC:61133-5482-5	160 g in 1 POUCH	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANADA	ANADA200377	12/06/2004			

Labeler - Bimeda, Inc. (060492923)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda, Inc.		060492923	manufacture

Revised: 3/2024

Bimeda, Inc.