

NADA Number: 111-636

Trade Name	Lincomix® Soluble Powder
Sponsor	Zoetis Inc.
Ingredients	Lincomycin Hydrochloride
Species	BEES (Honey bees) CHICKENS (Chicken, broilers excluding layers and breeders) SWINE (Swine, no use class stated or implied)
Routes of Administration	ORAL
Dosage Form	SOLUBLE POWDER
Dispensing Status	OTC
Exclusivity	Under section 573(c) of the Federal Food, Drug and Cosmetic Act (the Act), the approval for the control of American foulbrood (<i>Paenibacillus larvae</i>) in honey bees qualifies for SEVEN years exclusive marketing rights beginning on the date of approval because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the Act. (Expires March 27, 2019)
Dosage Amount, Indications & Limitations	<p>520.1263c Lincomycin hydrochloride soluble powder.</p> <p>Specifications: Each gram of soluble powder contains lincomycin hydrochloride equivalent to 0.4 grams of lincomycin.</p> <p>Conditions of use:</p> <p>Swine: 250 milligrams per gallon of drinking water to provide 3.8 milligrams per pound of body weight per day.</p> <p>Indications: For the treatment of swine dysentery (bloody scours).</p> <p>Limitations: Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. The safety of lincomycin has not been demonstrated in pregnant swine or swine intended for breeding.</p> <p>Chickens: 64 milligrams per gallon of drinking water.</p> <p>Indications: For the control of necrotic enteritis caused by <i>Clostridium perfringens</i> susceptible to lincomycin in broiler chickens.</p> <p>Limitations: Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens.</p> <p>Honey Bees: 100 mg per hive weekly for 3 weeks.</p> <p>Indications: For the control of American foulbrood (<i>Paenibacillus larvae</i>) in honey bees.</p>
Tolerances	Lincomycin Hydrochloride: A tolerance for residues of lincomycin in chickens is not required. Tolerances for lincomycin in swine of 0.6 part per million in liver and 0.1 part per million in muscle are established.