NADA Number: 013-076	
Trade Name	Tylan® Soluble
Sponsor	Elanco Animal Health, A Division of Eli Lilly & Co.
Ingredients	Tylosin Tartrate
Species	**BEES** (Honey bees) **CHICKENS** (Chicken, broilers) **CHICKENS** (Chicken, not laying eggs for human consumption) **CHICKENS** (Chicken, replacements) **SWINE** (Swine, no use class stated or implied) **TURKEYS** (Turkey, not laying eggs for human consumption)
Routes of Administration	Per Os
Dosage Form	SOLUBLE POWDER
Dispensing Status	RX
Patent Number (Expiration Date)	4048268 (No Expiration Date) 4283388 (No Expiration Date)
Exclusivity	This supplemental approval for TYLAN Soluble qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act because the supplemental approval included effectiveness studies. This exclusivity begins as of the date of our approval letter and only applies to the indication "for the control of mortality caused by necrotic enteritis (NE) associated with Clostridium perfringens in broiler chickens" (Expires 7/30/2017).
Dosage Amount, Indications & Limitations	**Chickens** Amount: 851 to 1,419 mg/gallon (225 to 375 ppm) in drinking water Administer medicated drinking water for a single five day period in broiler chickens. To assure all birds receive the intended medication, only medicated water should be available. These practices should be followed to assure both food safety and responsible antimicrobial drug use in chickens: 1) Use in flocks exhibiting signs of a necrotic enteritis outbreak, for example, increased mortality and lesions characteristic of necrotic enteritis upon necropsy; 2) Administer the full dose and dosing regimen once medication is initiated; 3) Use of Tylan Soluble or another macrolide is not advised if additional therapy is needed beyond the original course of medication. Indications: For the control of mortality caused by necrotic enteritis (NE) associated with *Clostridium perfringens* in broiler chickens. Limitations: Chickens must not be slaughtered for food within 24 hours after treatment. Do not use in layers producing eggs for human consumption. Prepare a fresh solution every 3 days. Amount: 2,000 mg/gallon (528 ppm) in drinking water Administer from 1 to 5 days as sole source of drinking water. Treated chickens must consume enough medicated drinking water to provide 50 milligrams of tylosin per pound of body weight per day. Indications: As an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* in broiler and replacement chickens. For the control of CRD associated with *Mycoplasma gallisepticum* at the time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens. Limitations: Chickens must not be slaughtered for food within 24 hours after treatment. Do not use in layers producing eggs for human consumption. Prepare a fresh solution every 3 days. **Turkeys** Amount: 2,000 mg/gallon (528 ppm) in drinking water Administer from 2 to 5 days as sole source of drinking water. Treated turkeys must consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day. Indications: For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum*. Limitations: Do not use in layers producing eggs for human consumption. Administer from 2 to 5 days as sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day. Prepare a fresh solution every 3 days. When sinus swelling is present, inject the sinus with tylosin injectable simultaneously with the drinking water treatment. **Swine** Amount: 250 mg/gallon (66 ppm) in drinking water Administer medicated drinking water for 3 to 10 days, depending upon severity of infection.

	Alternatively, administer medicated drinking water for 3 to 10 days, followed by 40 to 100 g tylosin per ton of complete feed (Type C medicated feed manufactured from TYLAN Type A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with TYLAN Soluble. Indications: For the treatment and control of swine dysentery (SD) associated with *Brachyspira hyodysenteriae*. For the treatment and control of swine dysentery (SD) associated with *Brachyspira hyodysenteriae* when followed immediately by TYLAN Type A medicated article in feed. Limitations: Swine must not be slaughtered for food within 48 hours after treatment. Prepare a fresh solution every 3 days. Amount: 250 mg/gallon (66 ppm) in drinking water Administer medicated drinking water for 3 to 10 days, followed by 40 to 100 g of tylosin per ton of complete feed (Type C medicated feed manufactured from TYLAN A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with TYLAN Soluble. Indications: For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* when followed immediately by TYLAN Type A medicated article in feed. Limitations: Swine must not be slaughtered for food within 48 hours after treatment. Prepare a fresh solution every 3 days. **Honey bees** Amount: 200 mg/colony in 20 g confectioners/powdered sugar Administer three treatments of medicated confectioners sugar once weekly for 3 weeks. The 200 mg dose is applied (dusted) over the top bars of the brood chamber. Indications: For the control of American Foulbrood (*Paenibacillus larvae*). Limitations: The drug should be fed early in the spring or 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. Use medicated sugar mixture immediately.
Tolerances	Tylosin Tartrate: Tolerances are established for residues of tylosin in edible products of animals as follows: a. Chickens and turkeys: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney. c. Swine: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney. e. Eggs: 0.2 part per million (negligible residue).