Food and Drug Administration, HHS

§ 520.154 Bacitracin oral dosage forms.

§ 520.154a Soluble bacitracin methylene disalicylate.

(a) Specifications. Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d) of this section.

(b) Sponsor. See No. 046573 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.70 of this chapter.

(d) Conditions of use—(1) Growing turkeys—(i) Amount. 400 milligrams per gallon in drinking water.

(ii) Indications for use. Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(iii) Limitations. Prepare a fresh solution daily.

(2) Broiler and replacement chickens—

(i) Amount. 100 milligrams per gallon in drinking water.

(A) Indications for use. Aid in the prevention of necrotic enteritis caused by Clostridium perfringens susceptible to bacitracin methylene disalicylate.

(B) Limitations. Prepare a fresh solution daily.

(ii) Amount. 200 to 400 milligrams per gallon in drinking water.

(A) Indications for use. Aid in the control of necrotic enteritis caused by C. perfringens susceptible to bacitracin methylene disalicylate.

(B) Limitations. Prepare a fresh solution daily.

(3) Swine—(i) Amount. 1 gram per gallon in drinking water.

(ii) Indications for use. Treatment of swine dysentery associated with Treponema hyodysenteriae. Administer continuously for 7 days or until signs of dysentery disappear.

(iii) Limitations. Prepare a fresh solution daily. Treatment not to exceed 14 days. If symptoms persist after 4 to 5 days consult a veterinarian. Not to be given to swine that weigh more than 250 pounds.

(4) Growing quail—(1) Amount. 400 milligrams per gallon in drinking water.

(ii) Indications for use. For prevention of ulcerative enteritis due to Clostridium coli susceptible to bacitracin methylene disalicylate.

(iii) Limitations. Prepare fresh solution daily. Use as sole source of drinking water.

§ 520.154b Bacitracin methylene disalicylate and streptomycin sulfate powder.

(a) Specifications. Each gram of powder contains 200 units bacitracin methylene disalicylate and streptomycin sulfate equivalent to 20 milligrams of streptomycin.

(b) Sponsor. See No. 046573 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Administer 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) Indications for use. For the treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as Escherichia coli, Proteus spp., Staphylococcus spp., and Streptococcus spp., and for the symptomatic treatment of associated diarrhea.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.154c Bacitracin zinc soluble powder.

(a) Specifications. Each pound contains the equivalent of not less than 5 grams of bacitracin.

(b) Sponsor. See No. 053501 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.70 of this chapter.
§ 520.182 Bicyclohexylammonium fumagillin.

(a) Specifications. The drug is a soluble powder containing bicyclohexylammonium fumagillin and appropriate phosphate buffers.

(b) Sponsor. See No. 059620 in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is used for the prevention of nosema in honey bees.1

(2) It is administered usually in a 2:1 sugar sirup containing a concentration of from 75 to 100 milligrams of fumagillin activity per gallon of sugar sirup.1

(3) Colonies used for package production should be fed medicated sirup as a principal food supply for a month prior to stocking nuclei or shaking packages for market.1

1These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

(d) Conditions of use—(1) Broiler chickens—(i) Amount. 100 milligrams per gallon in drinking water.

(A) Indications for use. Prevention of necrotic enteritis caused by Clostridium perfringens susceptible to bacitracin zinc.

(B) Limitations. Prepare a fresh solution daily.

(ii) Amount. 200 to 400 milligrams per gallon in drinking water.

(A) Indications for use. Control of necrotic enteritis caused by Clostridium perfringens susceptible to bacitracin zinc.

(B) Limitations. Prepare a fresh solution daily.

(2) Growing quail—(i) Amount. 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams per gallon in drinking water for 10 days.

(ii) Indications for use. Control of ulcerative enteritis caused by Clostridium spp. susceptible to bacitracin zinc.

(iii) Limitations. Prepare a fresh solution daily.


§ 520.222 Bunamidine hydrochloride.

(a) Chemical name. N,N-Dibutyl-4-(hexyloxy)-1-naphthamidine hydrochloride.

(b) Specifications. The drug is an oral tablet containing 100, 200, or 400 milligrams of bunamidine hydrochloride.

(c) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(d) Conditions of use. (1) The drug is intended for oral administration to dogs for the treatment of the tapeworms Dipylidium caninum, Taenia pisiformis, and Echinococcus granulosus, and to cats for the treatment of the tapeworms Dipylidium caninum and Taenia taeniaeformis.

(2) It is administered to cats and dogs at the rate of 25 to 50 milligrams per kilogram of body weight. The drug should be given on an empty stomach and food should not be given for 3 hours following treatment.

(3) Tablets should not be crushed, mixed with food, or dissolved in liquid. Repeat treatments should not be given within 14 days. The drug should not be given to male dogs within 28 days prior to their use for breeding. Do not administer to dogs or cats having known heart conditions.

(4) For use only by or on the order of a licensed veterinarian.


§ 520.246 Butorphanol tartrate tablets.

(a) Specifications. Each tablet contains 1, 5, or 10 milligrams of butorphanol base activity as butorphanol tartrate.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. The drug is used for the treatment of dogs as follows:

(1) Amount. 0.25 milligram of butorphanol base activity per pound of body weight.