Food and Drug Administration, HHS

§ 520.2325 Sulfadiazine oral dosage forms.

§ 520.2325a Sulfadiazine drinking water.

(a) Sponsor. See §510.600(c) of this chapter for identification of the sponsors.

(1) To No. 000859 for use of a 25-percent sulfadiazine soluble powder and a 20-percent sulfadiazine sodium solution as provided for in paragraph (c) of this section.

(2) To No. 061623 for use of 3.44- and 12.85-percent sulfadiazine sodium solutions as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) To No. 046573 for use of a 31.92-percent sulfadiazine solution (sodium and potassium salts) as provided in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(4) No. 053501 for use of a 28.62-percent sulfadiazine sodium solution as provided in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(b) Related tolerances. See §556.685 of this chapter.

(c) Conditions of use. It is used in drinking water as follows:

(1) Chickens. (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti*.

(ii) Administer at the 0.04 percent level for 2 or 3 days, skip 3 days then administer at the 0.025 percent level for 2 more days. If bloody droppings appear, repeat treatment at the 0.025 percent level for 2 more days. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(2) Turkeys. (i) As an aid in the control of outbreaks of coccidiosis caused by *Eimeria meleagritidis* and *E. adenoeides*.

(ii) Administer at the 0.025 percent level for 2 days, skip 3 days, give for 2 days, skip 3 days and give for 2 more days. Repeat if necessary. Do not change litter unless absolutely necessary. Do not give flushing mashes.

(3) Chickens and turkeys. (i) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfadiazine and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfadiazine.

(ii) Administer at the 0.04 percent level for 2 or 3 days. Move birds to clean ground. If disease recurs, repeat treatment. If cholera has become established as the respiratory or chronic form, use feed medicated with sulfadiazine. Poultry which have survived typhoid outbreaks should not be kept for laying house replacements or breeders unless tests show they are not carriers.

(4) Cattle and calves. (i) For the control and treatment of outbreaks of coccidiosis caused by *Eimeria bovis* or *E. zurnii*.

(ii) Administer at the 0.015-percent level for 3 to 5 days in drinking water medicated with sulfadiazine solution.

(iii) In lieu of treatment as provided in paragraph (e)(4)(ii) of this section, administer 1 teaspoon of 25-percent sulfadiazine soluble powder per day for each 125 pounds of body weight for 3 to 5 days in drinking water.

(d) Limitations. Consult a veterinarian or poultry pathologist for diagnosis. May cause toxic reactions unless the drug is evenly mixed in water at dosages indicated and used according to directions. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Medicated chickens, turkeys, cattle, and calves must actually consume enough medicated water which provides a recommended dosage of approximately 10 to 45 milligrams per pound per day in chickens, 3.5 to 55 milligrams per pound per day in turkeys, and approximately 6 milligrams
§ 520.2325b Sulfamethazine oral solution.

(a) Specifications. Each bottle contains 250 milligrams (mg) sulfamethazine.

(b) Sponsor. See No. 000672 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer one bottle orally per 4 pounds of body weight. The initial dose for treatment of disease should be administered every 12 hours; for use as a prophylactic, every 24 hours.

(2) Indications for use. Use as a prophylactic in dogs and cats as an aid in the treatment of respiratory infections caused by organisms sensitive to sulfamethazine.

(3) Limitations. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Do not use in lactating dairy cattle. Do not medicate dogs or cats producing eggs for human consumption. Make fresh drinking water daily.


§ 520.2327 Sulfadimethoxine oral solution.

(a) Specifications. Each bottle contains 250 milligrams (mg) sulfadimethoxine.

(b) Sponsor. See No. 000672 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer one bottle orally per 4 pounds of body weight.

(2) Indications for use. Use in dogs and cats as a prophylactic as an aid in the treatment of respiratory infections caused by organisms sensitive to sulfadimethoxine.

(3) Limitations. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Do not use in lactating dairy cattle. Do not medicate dogs or cats producing eggs for human consumption. Make fresh drinking water daily.