§ 520.2215  

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

[75 FR 10166, Mar. 5, 2010]

§ 520.2215 Sulfadiazine/pyrimethamine suspension.

(a) Specifications. Each milliliter (mL) of suspension contains 250 milligrams (mg) sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine.

(b) Sponsor. See No. 055246 in § 510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount. Administer orally 20 mg sulfadiazine per kilogram (kg) body weight and 1 mg/kg pyrimethamine daily.

(2) Indications for use. For the treatment of equine protozoal myeloencephalitis (EPM) caused by Sarcocystis neurona.

(3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use only by or on the order of a licensed veterinarian.


§ 520.2218 Sulfamerazine, sulfamethazine, and sulfaquinoxaline powder.

(a) Specifications. Each 195-gram (g) packet of powder contains 78 g sulfamerazine, 78 g sulfamethazine, and 39 g sulfaquinoxaline.

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

(c) Related tolerances. See §§ 556.670 and 556.685 of this chapter.

(d) Conditions of use—(1) Chickens—(i) Amounts and indications for use—(A) As an aid in the control of coccidiosis caused by Eimeria tenella and E. necatrix susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days. Repeat if necessary. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by Pasteurella multocida susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 days. If disease recurs, repeat treatment.

(ii) Limitations. Make fresh solution daily. Do not treat chickens within 14 days of slaughter for food. Do not medicate chickens producing eggs for human consumption.

(2) Turkeys—(i) Amounts and indications for use—(A) As an aid in the control of coccidiosis caused by Eimeria meleagrimitis and E. adenoeides susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.25 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days. Repeat if necessary. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by Pasteurella multocida susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

(ii) Limitations. Make fresh solution daily. Do not treat turkeys within 14 days of slaughter for food. Do not medicate turkeys producing eggs for human consumption.

[71 FR 13001, Mar. 14, 2006]

§ 520.2220 Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) Approvals. (1) For oral solution containing 12.5 percent (3.75 grams per ounce) sulfadimethoxine, see Nos. 000069, 000859, 054628, 054925, and 057561 in § 510.600(c).

(2) For soluble powder, each 107 grams contain the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt); see Nos. 000069, 054925, 057561, 058829, 061623, and 066104 in § 510.600(c) of this chapter.

(b) Special considerations. Federal law prohibits the extralabel use of this product in lactating dairy cattle.

(c) Related tolerances. See § 556.640 of this chapter.

(d) Conditions of use. The oral solution is administered as a cattle drench
Food and Drug Administration, HHS § 520.2220b

or diluted as directed to prepare drinking water. The powder is used to prepare a drench or drinking water. The concentrations and uses of the various solutions are as follows:

(1) **Broiler and replacement chickens only**—

(i) **Amount.** 1.875 (0.05 percent) grams per gallon.

(ii) **Indications for use.** Treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

(iii) **Limitations.** Administer for 6 consecutive days; do not administer to chickens over 16 weeks of age; as sole source of drinking water and sulphonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(2) **Meat-producing turkeys only**—

(i) **Amount.** 0.938 (0.025 percent) grams per gallon.

(ii) **Indications for use.** Treatment of disease outbreaks of coccidiosis and fowl cholera.

(iii) **Limitations.** Administer for 6 consecutive days; do not administer to turkeys over 24 weeks of age; as sole source of drinking water and sulphonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(3) **Dairy calves, dairy heifers, and beef cattle only**—

(i) **Amount.** 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon.

(ii) **Indications for use.** For the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Fusobacterium necrophorum (Sphaerophorus necrophorus) sensitive to sulfadimethoxine.

(iii) **Limitations.** Do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

§ 520.2220b Sulfadimethoxine tablets and boluses.

(a) **Sponsors.** Approval to firms identified in §510.600(c) of this chapter as follows:

(1) To 000069, approval for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

(2) To 000061, approval for use as in paragraph (d)(2).

(b) **Related tolerances.** See §556.640 of this chapter.

(c) [Reserved]

(d) **Conditions of use—**

(1) **Cattle**—

(i) **Amount.** Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat for 4 to 5 days.

(ii) **Indications for use.** For the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Fusobacterium necrophorum sensitive to sulfadimethoxine.

(iii) **Limitations.** Do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) **Dogs and cats**—

(i) **Amount.** Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours.

(ii) **Indications for use.** Treatment of sulfadimethoxine-susceptible bacterial infections.

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