

weight per day for the next 4 consecutive days; in drinking water or drench; available as a sulfadimethoxine soluble powder or a 12.5 percent sulfadimethoxine sodium solution (3.75 grams sulfadimethoxine per fluid ounce); if no improvement within 2 to 3 days, reevaluate diagnosis; do not treat beyond 5 days; withdraw 7 days before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[40 FR 13838, Mar. 27, 1975, as amended at 58 FR 6092, Jan. 26, 1993; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 8371, Feb. 25, 1997; 62 FR 23357, Apr. 30, 1997; 62 FR 35076, June 30, 1997; 62 FR 40932, July 31, 1997; 63 FR 59714, Nov. 5, 1998; 64 FR 18572, Apr. 15, 1999; 70 FR 73137, Dec. 9, 2005; 71 FR 13542, Mar. 16, 2006; 74 FR 60156, Nov. 20, 2009]

§ 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) It is used as follows:

(1) *Cattle*—(i) *Amount.* 1.25 to 2.5 grams per 100 pounds body weight.

(ii) *Indications for use.* Treatment of foot rot, bacterial pneumonia, shipping fever, and calf diphtheria.

(iii) *Limitations.* 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 from 4 to 5 days; 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.* 12.5 to 25 milligrams per pound of body weight.

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

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

(3) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* 12.5-gram-sustained-release bolus.

(ii) *Indications for use.* Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella spp.* sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

(iii) *Limitations.* Administer one bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days. Do not use in lactating dairy cattle. Do not administer within 12 days of slaughter. During treatment make certain that animals maintain adequate water intake. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 43488, Sept. 22, 1975; 49 FR 36830, Sept. 20, 1984; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997; 64 FR 15684, Apr. 1, 1999; 70 FR 16934, Apr. 4, 2005]

§ 520.2220c Sulfadimethoxine oral suspension.

(a) *Chemical name.* *N*-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) *Specifications.* Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.

(c) *Sponsor.* See Nos. 000061 and 000069 in § 510.600(c) of this chapter.

(1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

(2) On the first day of treatment administer an oral dose of 25 milligrams per pound of body weight, then follow with a daily dosage of 12.5 milligrams per pound of body weight. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours.

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Maintain adequate water intake during the treatment period.

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

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2220d Sulfadimethoxine-ormetoprim tablets.

(a) *Specifications.* Each tablet contains 120 milligrams (100 milligrams of sulfadimethoxine and 20 milligrams of ormetoprim), 240 milligrams (200 milligrams of sulfadimethoxine and 40 milligrams of ormetoprim), 600 milligrams (500 milligrams of sulfadimethoxine and 100 milligrams of ormetoprim), or 1200 milligrams (1,000 milligrams of sulfadimethoxine and 200 milligrams of ormetoprim).

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* On the first day of treatment, administer 25 milligrams per pound (55 milligrams per kilogram) of body weight. Then follow with a daily dosage of 12.5 milligrams per pound (27.5 milligrams per kilogram) of body weight.

(2) *Indications of use.* Treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of *Staphylococcus aureus* and *Escherichia coli* and urinary tract infections caused by *Escherichia coli*, *Staphylococcus* spp., and *Proteus mirabilis* susceptible to ormetoprim-potentiated sulfadimethoxine.

(3) *Limitations.* Continue treatment until patient is asymptomatic for 48 hours, but do not exceed a total of 21 consecutive days. Maintain adequate water intake during the treatment period. Safety in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 48593, Nov. 24, 1989, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 61 FR 46719, Sept. 5, 1996]

§ 520.2240 Sulfaethoxyypyridazine.

§ 520.2240a Sulfaethoxyypyridazine drinking water.

(a) *Chemical name.* N'-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range of 180 °C. to 186 °C.

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

(d) *Related tolerances.* See § 556.650 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Swine*—(i) *Amount.* 1.9 to 3.8 grams per gallon (0.05 percent to 0.1 percent).

(ii) *Indications for use.* Treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.

(iii) *Limitations.* Administer 3.8 grams per gallon for first day followed by 1.9 grams per gallon for not less than 3 days nor more than 9 days as sodium sulfaethoxyypyridazine; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 2.5 grams per gallon (0.066 percent).

(ii) *Indications for use.* Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days; as sodium sulfaethoxyypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food.

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.2240b Sulfaethoxyypyridazine tablets.

(a) *Chemical name.* N'-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range of 180 °C to 186 °C.

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

(d) *Related tolerances.* See § 556.650 of this chapter.

(e) *Conditions of use.* It is used for cattle as follows:

(1) *Amount.* 2.5 or 15 grams per tablet.

(i) *Indications for use.* Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as