Food and Drug Administration, HHS

§ 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 (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.

(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 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.

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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.

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

(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 Fusobacterium necrophorum sensitive to sulfadimethoxine.

(iii) Limitations. Do not use in female dairy cattle 20 months of age or older. Do not administer within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 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.

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine drinking water.

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