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(*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), coccidiosis (*Eimeria bovis* and *Eimeria zurnii*).

(B) *Horses*. Treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles (*Streptococcus equi*), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations*. Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Do not treat cattle within 10 days of slaughter. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

(b)(1) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter for use of 5-gram sulfamethazine bolus.

(2) *Related tolerances in edible products*. See § 556.670 of this chapter.

(3) *Conditions of use*—(i) *Amount*. Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use*. Ruminating beef and dairy calves. For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacilloosis) caused by *E. coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *F. necrophorum*; bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *E. bovis* and *E. zurnii*.

(iii) *Limitations*. Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20

months of age or older; such use may cause drug residues in milk. Administer with adequate supervision. Follows recommended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

[54 FR 15751, Apr. 19, 1989; 54 FR 19283, May 4, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 64 FR 66383, Nov. 26, 1999; 67 FR 78355, Dec. 24, 2002; 75 FR 10166, Mar. 5, 2010; 76 FR 17337, Mar. 29, 2011]

§ 520.2260b Sulfamethazine sustained-release boluses.

(a)(1) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine prolonged-release bolus.

(2) *Conditions of use*—(i) *Amount*. Depending on the duration of therapeutic levels desired, administer boluses as a single dose as follows: 3½ days—1 bolus (22.5 grams) per 200 pounds of body weight; 5 days—1 bolus per 100 pounds of body weight.

(ii) *Indications for use*. Beef and non-lactating cattle for sustained treatment of shipping fever pneumonia caused or complicated by *Pasteurella multocida*; as an aid in the treatment of foot rot, mastitis, pneumonia, metritis, bacterial enteritis, calf diphtheria, and septicemia when caused or complicated by bacteria susceptible to sulfamethazine.

(iii) *Limitations*. Cattle that are acutely ill should be treated parenterally with a suitable antibacterial product to obtain immediate therapeutic blood levels; do not slaughter animals for food within 16 days of treatment; do not use in lactating dairy cattle; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter for use of a 27-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. 27 grams (1 bolus) for each 150 pounds of body weight as a single dose.

(ii) *Indications for use*. For non-lactating cattle for the treatment of infections caused by organisms sensitive to sulfamethazine such as hemorrhagic septicemia (shipping fever complex),

bacterial pneumonia, foot rot, and calf diphtheria and as an aid in the control of bacterial diseases usually associated with shipping and handling of cattle.

(iii) *Limitations*. If no response within 2 to 3 days, reevaluate therapy; do not crush tablets; treated animals must not be slaughtered for food within 28 days after the latest treatment; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter for use of a 32.1-gram sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. 32.1 grams (1 bolus) per 200 pounds of body weight.¹

(ii) *Indications for use*. For beef and nonlactating dairy cattle for the treatment of diseases caused by sulfamethazine-sensitive organisms as follows: bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *E. coli*, necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*, and acute mastitis and acute metritis caused by *Streptococcus* spp.)¹

(iii) *Limitations*. After 72 hours, all animals should be reexamined for persistence of observable disease signs. If signs are present, consult a veterinarian. It is strongly recommended that a second dose be given to provide for an additional 72 hours of therapy, particularly in more severe cases. The dosage schedule should be used at each 72-hour interval. Animals should not receive more than 2 doses because of the possibility of incurring residue violations. This drug, like all sulfonamides, may cause toxic reactions and irreparable injury unless administered with adequate and continuous supervision; *follow dosages carefully*. Fluid intake must be adequate at all times throughout the 3-day therapy. Do not use in lactating dairy cattle. Do not treat animals within 12 days of slaughter.

¹These conditions are NAS/NRC reviewed and found 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)(1) *Sponsor*. See 000859 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine sustained release bolus.

(2) *Conditions of use*—(i) *Amount*. Administer 1 bolus (22.5 grams) per 200 pounds of body weight, as a single dose.

(ii) *Indications for use*. Beef and nonlactating dairy cattle for the prolonged treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), bacterial pneumonia (*Pasteurella* spp.), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), colibacillosis (bacterial scours) (*Escherichia coli*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.) and acute metritis (*Streptococcus* spp.).

(iii) *Limitations*. Cattle that are acutely ill should be treated by injection with a suitable antibacterial product to obtain immediate therapeutic blood levels; do not slaughter animals for food within 16 days of treatment; do not use in lactating dairy cattle; if treated animals do not respond within 2 to 3 days, consult a veterinarian.

(e)(1) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter for use of an 8.02-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. Administer 2 boluses (8.02 grams per bolus) per 100 pounds of body weight, as a single dose.

(ii) *Indications for use*. Administer orally to ruminating calves for the prolonged treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bacterial pneumonia (*Pasteurella* spp.), colibacillosis (bacterial scours) (*E. coli*), and calf diphtheria (*Fusobacterium necrophorum*).

(iii) *Limitations*. For use in ruminating replacement calves only; 72 hours after dosing all animals should be reexamined for persistence of disease signs; if signs are present, consult a veterinarian; do not slaughter animals for food for at least 12 days after the last dose; this product has not been

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shown to be effective for nonruminating calves; exceeding two consecutive doses may cause violative tissue residue to remain beyond the withdrawal time; do not use in calves under 1 month of age or calves being fed an all milk diet.

(f)(1) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter for use of a 30-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer at the rate of 1 bolus (30 grams per bolus) per 200 pounds of body weight, as a single dose.

(ii) *Indications for use.* Administer orally to beef cattle and nonlactating dairy cattle for the treatment of the following diseases when caused by one or more of the listed pathogenic organisms sensitive to sulfamethazine: bovine respiratory disease complex (shipping fever complex) associated with *Pasteurella* spp.; bacterial pneumonia associated with *Pasteurell* spp.; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*; colibacillosis (bacterial scours) caused by *Escherichia coli*; coccidiosis caused by *Eimeria bovis* and *E. zurnii*; acute mastitis and metritis caused by *Streptococcus* spp.

(iii) *Limitations.* For use in beef cattle and nonlactating dairy cattle only; if symptoms persist for 2 or 3 days after use, consult a veterinarian; do not slaughter animals for food for at least 8 days after the last dose; do not use in lactating dairy cattle; do not administer more than two consecutive doses.

(g) *Related tolerances.* See § 556.670 of this chapter.

(h)(1) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for use of an 8.25-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount.* Administer at the rate of 1 bolus (8.25 grams per bolus) per 50 pounds of body weight, as a single dose. If signs of disease are significantly reduced, it is recommended that a second dose be given to provide an additional 72 hours of therapy.

(ii) *Indications for use.* Administer orally to ruminating beef and dairy calves for treatment of the following diseases when caused by one or more of the listed pathogenic organisms sus-

ceptible to sulfamethazine: bacterial pneumonia associated with *Pasteurella* spp.; colibacillosis (bacterial scours) caused by *Escherichia coli*; coccidiosis caused by *Eimeria bovis* and *E. zurnii*; and calf diphtheria caused by *Fusobacterium necrophorum*.

(iii) *Limitations.* Do not use in calves to be slaughtered under 1 month of age or calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older. If symptoms persist after 3 days, consult a veterinarian. Do not administer more than 2 consecutive doses. Do not slaughter animals for food for at least 8 days after the last dose. Do not crush bolus.

[46 FR 36132, July 14, 1981, as amended at 48 FR 18803, Apr. 26, 1983; 48 FR 32760, July 19, 1983; 49 FR 29057, July 18, 1984; 50 FR 49372, Dec. 2, 1985; 51 FR 30212, Aug. 25, 1986; 53 FR 40727, Oct. 18, 1988; 54 FR 14341, Apr. 11, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003; 70 FR 8290, Feb. 18, 2005; 78 FR 17596, Mar. 22, 2013]

§ 520.2260c Sulfamethazine sustained-release tablets.

(a) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter for use of an 8-gram sulfamethazine sustained-release tablet.

(b) *Conditions of use*—(1) *Amount.* 8 grams (1 tablet) per 45 pounds of body weight as a single dose.

(2) *Indications for use.* In calves for sustained treatment of pneumonia caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *Escherichia coli*; and calf diphtheria caused by *Fusobacterium necrophorum*.

(3) *Limitations.* If there is no response within 2 to 3 days, reevaluate therapy. Do not crush tablets. Treated animals must not be slaughtered for food within 18 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 26763, June 10, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996]