

§ 520.370

(2) Each milliliter of suspension constituted from powder contains 50 mg of cefadroxil.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*—(i) *Dogs*. Administer 10 mg per pound (1b) body weight twice daily orally.

(ii) *Cats*. Administer 10 mg/lb body weight once daily orally.

(2) *Indications for use*—(i) *Dogs*. For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *S. aureus*.

(ii) *Cats*. For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *S. aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

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

[75 FR 10165, Mar. 5, 2010]

§ 520.370 Cefpodoxime tablets.

(a) *Specifications*. Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

(b) *Sponsors*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 5 to 10 mg per kilogram (2.3 to 4.5 mg per pound) body weight daily for 5 to 7 days, or for 2 to 3 days beyond the cessation of clinical signs, up to a maximum of 28 days.

(2) *Indications for use*. For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *S. aureus*, *Streptococcus canis* (group G, -hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

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

[69 FR 52815, Aug. 30, 2004]

21 CFR Ch. I (4–1–10 Edition)

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a)(1) *Specifications*. Each tablet contains 100, 250, or 500 milligrams, 1 or 2.5 grams of chloramphenicol.

(2) *Sponsor*. In § 510.600(c) of this chapter: No. 000010 for 100-, 250-, and 500-milligram and 1-gram tablets; No. 000856 for 100-, 250-, and 500-milligram tablets; No. 017030 for 100-milligram tablets; No. 000010 for 100-, 250-, and 500-milligram and 1- and 2.5-gram tablets; No. 000069 for 250-milligram tablets.

(3) *Conditions of use*. *Dogs*—(i) *Amount*. 25 milligrams per pound of body weight every 6 hours.

(ii) *Indications for use*. Oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(iii) *Limitations*. Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. If no response to chloramphenicol therapy is obtained in 3 to 5 days, discontinue its use and review diagnosis. Not for animals which are raised for food production. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. Each tablet contains 50, 100, 250, or 500 milligrams, or 1 gram of chloramphenicol.

(2) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use*. *Dogs*—(i) *Amount*. 25 milligrams per pound of body weight every 6 hours.

(ii) *Indications for use*. Oral treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(iii) *Limitations*. Laboratory tests should be conducted, including in vitro