Food and Drug Administration, HHS

§ 520.390c

(c) Conditions of use in dogs
(1) Amount. Administer 25 mg per pound of body weight by mouth every 6 hours.
(2) Indications for use—(i) For the treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.
(ii) For the treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

§ 520.390b Chloramphenicol capsules.

(a) Specifications. Each capsule contains 50, 100, 250, or 500 milligrams (mg) chloramphenicol.
(b) Sponsors. See Nos. 000069 and 050057 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.
(c) Special considerations. Federal law prohibits the extralabel use of this product in food-producing animals.
(d) Conditions of use in dogs
(1) Amount. 25 mg per pound of body weight every 6 hours.
(2) Indications for use. For treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.390 Chloramphenicol oral suspension.

(a) Specifications. Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.
(b) Sponsor. See No. 000856 in § 510.600(c) of this chapter.

§ 520.390a Chloramphenicol tablets.

(a) Specifications. Each tablet contains 50, 100, 250, or 500 milligrams (mg); 1 or 2.5 grams (g) of chloramphenicol.
(b) Sponsors. See § 510.600(c) of this chapter:
(1) For use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section:
(i) No. 054628 for 100-, 250-, and 500-mg; and 1- and 2.5-g tablets;
(ii) No. 000856 for 100-, 250-, and 500-mg tablets;
(iii) No. 000069 for 250-mg tablets.
(2) For use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section:
(i) No. 061623 for 50-, 100-, 250-, and 500-mg; and 1-g tablets;
(ii) [Reserved]