

the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(b) *Conditions of use*—(1) *Dosage/indications for use.* (i) Three milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) Three milligrams per pound of body weight daily as an aid in the control of ascarid infections (*Toxocara canis*) in dogs.

(iii) Twenty-five to 50 milligrams per pound of body weight as an aid in the treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*).

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

[46 FR 23230, Apr. 24, 1981, as amended at 46 FR 41038, Aug. 14, 1981; 46 FR 46315, Sept. 18, 1981; 46 FR 61653, Dec. 18, 1981; 47 FR 10805, Mar. 12, 1982; 47 FR 14150, Apr. 2, 1982; 50 FR 41489, Oct. 11, 1985; 50 FR 49372, Dec. 2, 1985; 53 FR 40056, Oct. 13, 1988; 53 FR 40727, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003; 76 FR 17777, Mar. 31, 2011; 77 FR 4896, Feb. 1, 2012]

§ 520.622b Diethylcarbamazine citrate syrup.

(a)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

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

(3) *Conditions of use.* (i) The drug is indicated for use in dogs for the prevention of infection with *Dirofilaria immitis* and *T. canis* and *T. leonina*. It is also indicated for treatment of ascarid infections of *T. canis* and *T. leonina* in dogs and *T. cati* in cats.

(ii) For prevention of heartworm and ascarid infections in dogs, the drug may be added to the daily diet at a dosage rate of 3.0 milligrams per pound of body weight per day or given directly by mouth at the same dosage rate. For treatment of ascarid infections in dogs and cats, the drug is administered at a dosage level of 25 to 50 milligrams per pound of body weight preferably administered immediately after feeding.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration

of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administration of this drug.

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

(b) [Reserved]

(c)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

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

(3) *Conditions of use.* (i) The drug is used in dogs between 4 weeks and 8 months of age for the removal of ascarids (*Toxocara canis*) and in animals over 4 weeks of age for the prevention of heartworm disease (*Dirofilaria immitis*).

(ii) The drug is administered (a) for removal of ascarids at a dosage of 50 milligrams per pound of body weight divided into two equal doses and administered 8 to 12 hours apart (morning and night), orally or mixed with either dry or wet food, and (b) for prevention of heartworm disease at a dosage of 3 milligrams per pound of body weight daily, orally or in food, in heartworm endemic areas, from the beginning of mosquito activity, during the mosquito season, and for 2 months following the end thereof.

(iii) Dogs older than 8 months of age may be infected with *Dirofilaria immitis*. Use of the drug is contraindicated in dogs with active *D. immitis* infections.

(iv) 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 41 FR 28265, July 9, 1976; 44 FR 3967, Jan. 19, 1979; 47 FR 14150, Apr. 2, 1982; 47 FR 35186, Aug. 13, 1982; 49 FR 33997, Aug. 28, 1984; 50 FR 41489, Oct. 11, 1985; 53 FR 47027, Oct. 18, 1988; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997; 77 FR 4897, Feb. 1, 2012]

§ 520.622c Diethylcarbamazine citrate chewable tablets.

(a) *Specifications.* Each chewable tablet contains 30, 45, 60, 120, 150, or 180 milligrams of diethylcarbamazine citrate.

(b) *Sponsors.* See drug listing nos. in § 510.600(c) of this chapter for identification of sponsors as follows:

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- (1) [Reserved]
- (2) For 000069, use of 60, 120, or 180 milligram tablets as in paragraph (c)(2)(ii) of this section.
- (3) For 061690, use of 45 or 150 milligram tablets as in paragraph (c)(2)(iii) of this section.
- (4) For 061133, use of 60-, 120-, or 180-milligram tablets as in paragraph (c)(2)(i) of this section.
- (5) For 000061, use of 60-milligram tablets as in paragraph (c)(2)(i) of this section.
- (6) For 000010, use of 30, 60, 120, or 180 milligram tablets as in paragraph (c)(2)(i) of this section.
- (c) *Conditions of use*—(1) *Amount*. 3 milligrams per pound of body weight per day for prevention of heartworm disease and control of ascarids; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.
- (2) *Indications for use*. (i) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs; as an aid in control of ascarids (*Toxocara canis*) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs and cats.
- (ii) For prevention of infection with *Dirofilaria immitis* (heartworm disease) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs.
- (iii) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 6941, Feb. 17, 1978]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.622c, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 520.622d Diethylcarbamazine citrate capsules.

- (a) *Specifications*. Each capsule contains 12.5, 50, 200, or 400 milligrams (mg) diethylcarbamazine citrate.
- (b) *Sponsor*. See No. 011014 in § 510.600(c) of this chapter.
- (c) *Conditions of use in dogs*—(1) *Amount/indications for use*. 3 mg per pound (lb) body weight daily for prevention of heartworm disease (*Dirofilaria immitis*); 25 to 50 mg/lb body

weight in a single dose as an aid in the treatment of ascarid infections (*Toxocara canis* and *Toxascaris leonina*).

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

[70 FR 50182, Aug. 26, 2005]

§ 520.623 Diethylcarbamazine citrate, oxibendazole chewable tablets.

(a) *Specifications*. Each tablet contains either 60, 120, or 180 milligrams of diethylcarbamazine citrate with 45, 91, or 136 milligrams of oxibendazole, respectively.

(b) *Sponsor*. See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally to dogs at a dosage level of 6.6 milligrams of diethylcarbamazine citrate per kilogram of body weight (3 milligrams per pound of body weight) and 5.0 milligrams of oxibendazole per kilogram of body weight (2.27 milligrams per pound of body weight).

(2) *Indications for use*. For prevention of infection with *Dirofilaria immitis* (heartworm disease) and *Ancylostoma caninum* (hookworm infection) and for removal and control of *Trichuris vulpis* (whipworm infection) and mature and immature stages of intestinal *Toxocara canis* (ascarid infection).

(3) *Limitations*. Orally administer daily during heartworm season. For free-choice feeding or broken and placed on or mixed with feed. Do not use in dogs that may harbor adult heartworms. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 28768, July 16, 1985, as amended at 53 FR 45759, Nov. 14, 1988; 54 FR 3776, Jan. 26, 1989; 54 FR 6804, Feb. 14, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.645 Difloxacin.

(a) *Specifications*. Each tablet contains 11.4, 45.4, or 136 milligrams (mg) of difloxacin hydrochloride.

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

(c) [Reserved]

(d) *Conditions of use*—(i) *Amount*. Administer 5 to 10 mg per kilogram (2.3 to 4.6 mg per pound) of body weight orally