

§ 520.622d

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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

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once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days.

(ii) *Indications for use.* For management of diseases in dogs associated with bacteria susceptible to difloxacin.

(iii) *Limitations.* Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 8123, Feb. 18, 1998, as amended at 75 FR 10165, Mar. 5, 2010]

§ 520.666 Dirlotapide.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) dirlotapide.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* The initial dosage is 0.01 mL/kg (0.0045 mL/lb) body weight for the first 14 days. After the first 14 days of treatment, the dose volume is doubled to 0.02 mL/kg (0.009 mL/lb) body weight for the next 14 days (days 15 to 28 of treatment). Dogs should be weighed monthly and the dose volume adjusted every month, as necessary, to maintain a target percent weight loss until the desired weight is achieved.

(2) *Indications for use.* For the management of obesity.

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

[72 FR 263, Jan. 4, 2007]

§ 520.763 Dithiazanine iodide oral dosage forms.

§ 520.763a Dithiazanine iodide tablets.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinyliidene)-1,3-pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

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

(d) *Conditions of use.* (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara canis</i> , <i>Toxascaris leonina</i>)	10	3–5
Hookworms (<i>Ancylostoma caninum</i> , <i>Uncinaria stenocephala</i>)	10	7
Whipworms (<i>Trichuris vulpis</i>)	10	
Strongyloides (<i>Strongyloides canis</i> , <i>Strongyloides stercoralis</i>)	10	10–12
Heartworm microfilariae (<i>Dirofilaria immitis</i>)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

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

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed 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.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763b Dithiazanine iodide powder.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinyliidene)-1,3-pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

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

(d) *Conditions of use.* (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara canis</i> , <i>Toxascaris leonina</i>)	10	3–5