§ 520.622c

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the mosquito season and be continued daily throughout the mosquito season and for 2 months thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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.

(4) For 061690, use of 45 or 150 milligram tablets as in paragraph (c)(2)(ii) of this section.

(5) For 061133, use of 60-, 120-, or 180-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.

(7) [Reserved]

(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. Tablets are administered orally or pulverized and given in the feed. For treatment of ascarid infections, a repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestine from the lungs after the first dose. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start at the beginning of mosquito activity and be continued daily throughout the mosquito season.
and for approximately a month thereafter. 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 on GPO Access.

§ 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, 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/indications for use. 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. Oral administration 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.


§ 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 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 infections 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.

[63 FR 8123, Feb. 18, 1998, as amended at 75 FR 10165, March 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.