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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)(1) *Specifications.* Each capsule contains either 12.5, 50, 200, or 400 milligrams of diethylcarbamazine citrate.

(2) *Sponsor.* See 011014 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount/indications for use.* 3 milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs; 25 to 50 milligrams per pound of body weight in a single dose as an aid in the treatment of ascarid infections in dogs (*Toxocara canis* and *Toxascaris leonina*).

(ii) *Limitations.* Administer orally directly or added to the daily ration. For ascarid infections, repeat treatment in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Do not treat dogs with established heartworm infections 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 or shock. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should begin 1 month before and continue 2 months after the mosquito season. Dogs receiving prophylactic therapy should be examined every 6 months for the presence of microfilariae. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each capsule contains either 12.5, 50, 200, or 400 milligrams of diethylcarbamazine citrate.

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(2) *Sponsor.* See 023851 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Amount/indications for use.* 3 milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) *Limitations.* Capsules may be administered to the dog directly or added to the daily ration. For oral administration only. Do not treat dogs with established heartworm infections 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 or shock. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should begin 1 month before and continue 2 months after the mosquito season. Dogs receiving prophylactic therapy should be examined every 6 months for the presence of microfilariae. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 26377, June 18, 1982, as amended at 48 FR 46979, Oct. 17, 1983; 49 FR 5099, Feb. 10, 1984]

§ 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).

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(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. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* 5 to 10 mg per kilogram (2.3 to 4.6 mg/pound) of body weight.

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

(iii) *Limitations.* Use once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days. 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]

§ 520.763 Dithiazanine iodide oral dosage forms.

§ 520.763a Dithiazanine iodide tablets.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinylidene)-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-benzothiazolinylidene)-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 |