

§ 520.623

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).

(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.

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(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