

§ 520.1872

21 CFR Ch. I (4-1-03 Edition)

prior to or after treatment. If reinfection occurs, treatment may be repeated. Consult your veterinarian before giving to sick or pregnant animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) [Reserved]

[58 FR 58652, Nov. 3, 1993]

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

(a) *Specifications.* Each tablet contains either:

- (1) Tablet No. 1: 22.7 milligrams praziquantel, 22.7 milligrams pyrantel base, and 113.4 milligrams febantel; or
- (2) Tablet No. 2: 68 milligrams praziquantel, 68 milligrams pyrantel base, and 340.2 milligrams febantel.

(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* Administer as a single dose directly by mouth or in a small amount of food as follows:

Weight of animal		Number of tablets per dose	
Kilograms	Pounds	Tablet no. 1	Tablet no. 2
0.9 to 1.8	2 to 4	1/2	
2.3 to 3.2	5 to 7	1	
3.6 to 5.4	8 to 12	1 1/2	
5.9 to 8.2	13 to 18	2	
8.6 to 11.4	19 to 25	2 1/2	
11.8 to 13.6 ...	26 to 30		1
14.1 to 20.0 ...	31 to 44		1 1/2
20.4 to 27.2 ...	45 to 60		2
27.7 to 33.6 ...	61 to 74		2 1/2
34.0 to 40.9 ...	75 to 90		3
41.3 to 47.2 ...	91 to 104		3 1/2
47.7 to 54.5 ...	105 to 120		4

(ii) *Indications for use.* For the removal of tapeworms (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus*); hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*); ascarids (*Toxocara canis*, *Toxascaris leonina*); and whipworms (*Trichuris vulpis*) and for the removal and control of tapeworm *Echinococcus multilocularis* in dogs.

(iii) *Limitations.* Do not use in pregnant animals. Do not use in dogs weighing less than 0.9 kilogram (2 pounds) or puppies less than 3 weeks of age. Federal law restricts this drug to

use by or on the order of a licensed veterinarian.

[59 FR 33908, July 1, 1994, as amended at 61 FR 29651, June 12, 1996]

§ 520.1880 Prednisolone tablets.

(a) *Specifications.* Each tablet contains 5 or 20 milligrams prednisolone.

(b) *Sponsor.* See No. 061690 in § 510.600(c)(2) of this chapter.

(c) *Special considerations.* (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Do not use in viral infections. Systemic therapy with prednisolone is contraindicated in animals with peptic ulcer, corneal ulcer, and Cushingoid syndrome. The presence of diabetes, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, renal insufficiency, and active tuberculosis necessitates carefully controlled use. Some of the above conditions occur only rarely in dogs but should be kept in mind.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(d) *Conditions of use—(1) Amount.* Dogs: 2.5 milligrams per 4.5 kilograms (10 pounds) body weight per day. Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* For use in dogs as an anti-inflammatory agent.

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

[57 FR 4718, Feb. 7, 1992, as amended at 60 FR 57832, Nov. 22, 1995; 63 FR 148, Jan. 5, 1998]

§ 520.1900 Primidone tablets.

(a) *Specifications.* Each tablet contains 50 or 250 milligrams of primidone.