to 30 lb, 2 tablets (68 mg); 31 to 45 lb, 3 tablets (102 mg); 46 to 60 lb, 4 tablets (136 mg); over 60 lb, 5 tablets maximum (170 mg). Administer directly by mouth or crumbled and in feed.

(ii) *Indications for use*—(A) For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(B) For removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

(iii) *Limitations*—(A) If labeled only for use as in paragraph (c)(1)(ii)(A) of this section: Not intended for use in puppies less than 4 weeks of age. Consult your veterinarian before administering tablets to weak or debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(B) If labeled for use as in paragraph (c)(1)(ii)(B) of this section: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Indications for use*. For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis*.

(ii) *Dosage*. Cats 4 pounds and under, 11.5 mg; 5 to 11 pounds, 23 mg; over 11 pounds, 34.5 mg.

(iii) *Limitations*. Administer directly by mouth or crumbled and in feed. Not intended for use in kittens less than 6 weeks of age. For OTC use: Consult your veterinarian before administering tablets to weak or debilitated animals, and for assistance in the diagnosis, treatment, and control of parasitism.

[46 FR 60570, Dec. 11, 1981, as amended at 47 FR 26377, June 18, 1982; 55 FR 2234, Jan. 23, 1990; 58 FR 7864, Feb. 10, 1993; 58 FR 42853, Aug. 12, 1993; 68 FR 57351, Oct. 3, 2003; 69 FR 62181, Oct. 25, 2004]

§ 520.1871 Praziquantel and pyrantel.

(a) *Specifications*. (1) Each tablet contains 13.6 milligrams (mg) praziquantel and 54.3 mg pyrantel base (as pyrantel pamoate), 18.2 mg praziquantel and 72.6 mg pyrantel base (as pyrantel pamoate), or 27.2 mg praziquantel and 108.6 mg pyrantel base (as pyrantel pamoate).

(2) Each chewable tablet contains 30 mg praziquantel and 30 mg pyrantel pamoate or 114 mg praziquantel and 114 mg pyrantel pamoate.

(b) *Sponsors*. See sponsors in § 510.600(c) for use as in paragraph (d) of this chapter.

(1) See No. 000859 for use of tablets described in paragraph (a)(1) of this section for use as in paragraph (d)(1) of this section.

(2) See No. 051311 for use of tablets described in paragraph (a)(2) of this section for use as in paragraph (d)(2) of this section.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Cats*—(i) *Dosage*. Administer a minimum dose of 2.27 mg praziquantel and 9.2 mg pyrantel pamoate per pound of body weight according to the dosing tables on labeling. May be given directly by mouth or in a small amount of food. Do not withhold food prior to or after treatment. If reinfection occurs, treatment may be repeated.

(ii) *Indications for use*. For removal of tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*), hookworms (*Ancylostoma tubaeforme*), and large roundworms (*Toxocara cati*) in cats and kittens.

(iii) *Limitations*. Not for use in kittens less than 2 months of age or weighing less than 2.0 pounds. Consult your veterinarian before giving to sick or pregnant animals.

(2) *Dogs*—(i) *Amount*. Administer a minimum dose of 5 mg praziquantel and 5 mg pyrantel pamoate per kilogram body weight (2.27 mg praziquantel and 2.27 mg pyrantel pamoate per pound body weight) according to the dosing tables on labeling.

(ii) *Indications for use*. For the treatment and control of roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) in dogs and puppies.

[58 FR 58652, Nov. 3, 1993, as amended at 72 FR 16270, Apr. 4, 2007; 75 FR 54018, Sept. 3, 2010]

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

(a) *Specifications*. Each tablet or chewable 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.

(3) Tablet No. 3: 136 milligrams (mg) praziquantel, 136 mg pyrantel base, and 680.4 mg 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	Tablet no. 3
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	1
27.7 to 40.9	61 to 90	.....	.....	1 1/2
41.3 to 54.5	91 to 120	.....	.....	2

(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; 68 FR 22293, Apr. 28, 2003; 71 FR 6677, Feb. 9, 2006]

§ 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.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter for use of 250 milligram tablets; see No. 000856 in § 510.600(c) of this chapter for use of 50 and 250 milligram tablets.

(c) *Conditions of use in dogs*—(1) *Amount*. Twenty-five milligrams of primidone per pound of body weight (55 milligrams per kilogram of body weight) daily.[1]

[1] These conditions are 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

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