§ 520.1855 Ponazuril.

(a) *Specifications*. Each gram of paste contains 150 milligrams (mg) ponazuril.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 5 mg per kilogram body weight, daily for 28 days.

(2) *Indications for use*. For the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona*.

(3) *Limitations*. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 43774, Aug. 21, 2001]

§ 520.1870 Praziquantel tablets.

(a) *Specifications*. Each dog tablet contains 34 milligrams (mg) of praziquantel; each cat tablet contains 11.5 or 23 mg of praziquantel.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use*. For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*. If labeled for use by or on the order of a licensed veterinarian, for removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

(ii) *Dosage*. Dogs 5 pounds and under, ½ tablet (17 mg); 6 to 10 pounds, 1 tablet (34 mg); 11 to 15 pounds, 1½ tablets (51 mg); 16 to 30 pounds, 2 tablets (68 mg); 31 to 45 pounds, 3 tablets (102 mg); 46 to 60 pounds, 4 tablets (136 mg); over 60 pounds, 5 tablets maximum (170 mg).

(iii) *Limitations*. Administer directly by mouth or crumbled and in feed. Not intended for use in puppies less than 4 weeks of age. For over-the-counter (OTC) use: Consult your veterinarian before administering tablets to weak or debilitated animals, and for assistance in the diagnosis, treatment, and control of parasitism. For prescription use: 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]

§ 520.1871 Praziquantel/pyrantel pamoate tablets.

(a) *Specifications*. Each cat tablet contains 18.2 milligrams (mg) praziquantel with 72.6 mg pyrantel (as pyrantel pamoate).

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

(c) *Conditions of use*—(1) *Cats*—(i) *Dosage*. 1.5 to 1.9 pounds, 1/4 tablet; 2 to 3 pounds, 1/2 tablet; 4 to 8 pounds, 1 tablet; 9 to 12 pounds, 1 1/2 tablets; 13 to 16 pounds, 2 tablets.

(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 1 month of age or weighing less than 1.5 pounds. 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. 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.

(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]

(2) *Indications for use*. For the control of convulsions associated with idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease that occurs as a

[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 require bioequivalency and safety information.