

§ 520.1872

21 CFR Ch. I (4–1–14 Edition)

(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