

§ 520.1870

21 CFR Ch. I (4–1–11 Edition)

§ 520.1870 Praziquantel tablets.

(a) *Specifications.* Each tablet contains:

- (1) 34 milligrams (mg) praziquantel.
- (2) 11.5 or 23 mg praziquantel.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 000859 for use of the product described in paragraph (a)(1) of this section, as in paragraph (c)(1) of this section; and for use of the product described in paragraph (a)(2) of this section, as in paragraph (c)(2) of this section.

(2) No. 059130 for use of the product described in paragraph (a)(1) of this section, as in paragraph (c)(1) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 pounds (1b) and under, 1/2 tablet (17 mg); 6 to 10 lb, 1 tablet (34 mg); 11 to 15 lb, 1 1/2 tablets (51 mg); 16 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