

## § 520.300

884, or 1,768 milligram or 4.42 gram capsules; No. 038782 for 884 or 1,768 milligram or 4.42 gram capsules; and No. 054771 for 221 milligram capsules.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs.

(ii)(a) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks.

(b) The drug is administered orally to dogs. Capsules containing 221 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 1¼ pound of body weight. Capsules containing 442 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 2½ pounds body weight. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: Weighing under 5 pounds, 1 capsule; weighing 5 to 10 pounds, 2 capsules; weighing 10 to 20 pounds, 3 capsules; weighing 20 to 40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 5 to 10 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 40 pounds or over.

(iii) A veterinarian should be consulted before using in severely debilitated dogs.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39858, Aug. 29, 1975; 44 FR 10059, Feb. 16, 1979; 54 FR 38515, Sept. 19, 1989; 55 FR 24556, June 18, 1990; 64 FR 15684, Apr. 1, 1999; 70 FR 50182, Aug. 26, 2005; 78 FR 14669, Mar. 7, 2013; 79 FR 28818, May 20, 2014]

EDITORIAL NOTE: At 78 FR 14669, Mar. 7, 2013, §520.260 was amended by adding paragraphs (b)(1) through (3); however, the amendment could not be incorporated because (b)(1) through (3) already existed.

## 21 CFR Ch. I (4–1–15 Edition)

### § 520.300 Cambendazole oral dosage forms.

#### § 520.300a Cambendazole suspension.

(a) *Specifications.* Each fluid ounce contains 0.9 gram of cambendazole.

(b) *Sponsor.* No. 050604 in §510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer by stomach tube or as a drench at a dose of 0.9 gram of cambendazole per 100 pounds of body weight (20 milligrams per kilogram).

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

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

[40 FR 13838, Mar. 27, 1975. Redesignated at 41 FR 1276, Jan. 7, 1976, and amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997; 79 FR 28818, May 20, 2014]

#### § 520.300b Cambendazole pellets.

(a) *Specifications.* The drug is in feed pellets containing 5.3 percent cambendazole.

(b) *Sponsor.* No. 050604 in §510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 20 milligrams cambendazole per kilogram body weight (6 ounces per 1,000 pounds) by mixing with normal grain ration given at one feeding. Doses for individual horses should be mixed and fed separately to assure that each horse will consume the correct amount. For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(3) *Limitations.* Do not administer to pregnant mares during first 3 months

of pregnancy. Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997; 79 FR 28818, May 20, 2014]

#### § 520.300c Cambendazole paste.

(a) *Specifications.* The drug is a paste containing 45 percent cambendazole.

(b) *Sponsor.* No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 20 milligrams cambendazole per kilogram body weight (5 grams per 550 pounds (250 kilograms)) by depositing the paste on the back of the tongue using a dosing gun. For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(2) *Indications for use.* For the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(3) *Limitations.* Do not administer to pregnant mares during first 3 months of pregnancy. Do not use in horses intended for human consumption. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997; 79 FR 28819, May 20, 2014]

#### § 520.301 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of 5st caramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.

(2) *Indications for use.* For relief of cough.

[43 FR 55385, Nov. 28, 1978, as amended at 79 FR 28819, May 20, 2014. Redesignated at 80 FR 13229, Mar. 13, 2015]

#### § 520.302 Carnidazole tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of carnidazole.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).

(2) *Indications for use.* For treating trichomoniasis (canker) in ornamental and homing pigeons.

(3) *Limitations.* Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989. Redesignated at 80 FR 13229, Mar. 13, 2015]

#### § 520.304 Carprofen.

(a) *Specifications.* (1) Each caplet contains 25, 75, or 100 milligrams (mg) carprofen.

(2) Each chewable tablet contains 25, 75, or 100 mg carprofen.

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

(1) No. 054771 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) Nos. 000115, 000859, 055529, and 062250 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

(3) No. 026637 for use of product described in paragraph (a)(2) of this section as in paragraph (d) of this section.

(c) [Reserved]

(d) *Conditions of use in dogs—(1) Amount.* 2 mg per pound (lb) of body weight once daily or 1 mg/lb twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.