

Food and Drug Administration, HHS

§ 520.300c

(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]

§ 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.* (1) It is used in horses 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*).

(2) It is administered 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).

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) 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]

§ 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.* (1) It is used in horses 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*).

(2) 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.

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) 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]

§ 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.* (1) It is used in horses 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*).

(2) 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.

(3) 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.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

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(6) 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]

§ 520.309 Carprofen.

(a) *Specifications.* Each caplet or chewable tablet contains 25, 75, or 100 milligrams of carprofen.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs—(1) Amount.* 1 milligram per pound of body weight twice daily. Caplets and chewable tablets are scored and dosage should be calculated and given in half-caplet or half-chewable tablet increments.

(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis in dogs.

(3) *Limitations.* The safe use of carprofen in pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. As a class, cyclo-oxygenase inhibitory non-steroidal anti-inflammatory drugs (NSAID's) may be associated with gastrointestinal and renal toxicity. Patients at greatest risk for renal toxicity are those on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Because many NSAID's possess the potential to induce gastrointestinal ulceration, avoid or closely monitor concomitant use of carprofen with other anti-inflammatory drugs, such as corticosteroids and NSAID's. Carprofen treatment was not associated with renal toxicity or gastrointestinal ulceration in safety studies of up to 10 times the dose in dogs. Do not use in dogs with bleeding disorders (e.g., Von Willebrand's disease). Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66581, Dec. 18, 1996, as amended at 64 FR 32181, June 16, 1999]

§ 520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of 5stcaramiphen

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ethanedisulfonate and 80 milligrams of ammonium chloride.¹

(b) *Sponsor.* See No. 000856 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.¹

(2) *Indications for use.* For relief of cough.¹

[43 FR 55385, Nov. 28, 1978]

§ 520.312 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]

§ 520.314 Cefadroxil tablets.

(a) *Specifications.* 50-, 100-, and 200-milligram tablets for dogs and cats; 1 gram tablet for dogs.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) For use in dogs as follows:

(i) *Indications for use.* For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus*.

(ii) *Amount.* Ten milligrams per pound of body weight twice daily.

¹These 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.