

§ 520.563

21 CFR Ch. I (4-1-02 Edition)

(3) The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. Oral therapy in these cases is too slow. Animals which cannot drink after initial intravenous therapy may need to be dosed with a stomach tube or esophageal tube. Adequate colostrum intake during the first 12 hours is essential for healthy, vigorous calves. Antibacterial therapy is often indicated in bacterial scours due to *E. coli* and/or *Salmonella*. The product does not contain antibacterial agents. A veterinarian should be consulted in severely scouring calves or cases requiring antibacterial therapy. The product is not nutritionally complete if administered by itself for long periods of time. It should not be administered beyond the recommended treatment period without the addition of milk or milk replacer.

[48 FR 38606, Aug. 25, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.563 Diatrizoate meglumine and diatrizoate sodium oral solution.

(a) *Specifications.* Diatrizoate meglumine oral solution is a water soluble radiopaque medium containing 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for radiography of the gastrointestinal tract in dogs and cats.

(2) It is administered orally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. It is administered rectally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.580 Dichlorophene and toluene capsules.

(a) *Specifications.* Each soft gelatin capsule contains 50 milligrams of

dichlorophene and 60 milligrams of toluene or multiples thereof.¹

(b) *Sponsor.* (1) For single dose only, see 000010, 000061, 000115, 000842, 011615, 017135, 023851, 049968, 050906, and 058670 in § 510.600(c) of this chapter.

(2) For single and multiple dose, see 000010, 000061, and 038782 in § 510.600(c) of this chapter.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use—(1) Amount.* (i) Single dose of 100 milligrams of dichlorophene and 120 milligrams of toluene per pound of body weight.¹

(ii) Divided dose of 100 milligrams of dichlorophene and 120 milligrams of toluene per 5 pounds of body weight (20 and 24 milligrams per pound) daily for 6 days.¹

(2) *Indications for use.* It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) and as an aid in removing tapeworms (*Taenia pisiformis*, *Dipylidium caninum*, and *Echinococcus granulosus*) from dogs and cats.¹

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward. Repeat treatment in 2 to 4 weeks in animals subject to reinfection.¹

[45 FR 10332, Feb. 15, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.580, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 520.581 Dichlorophene tablets.

(a) *Specifications.* Each tablet contains 1 gram of dichlorophene.

(b) *Sponsor.* See 023851 in § 510.600(c) of this chapter.

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.

(c) *Required statement.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before administering to weak or debilitated animals.

(d) *Conditions of use. Dogs*—(1) *Amount.* Single dose of 1 tablet (1 gram of dichlorophene) for each 10 pounds of body weight.

(2) *Indications for use.* It is used as an aid in the removal of tapeworms (*Taenia pisiformis* and *Dipylidium caninum*).

(3) *Limitations.* Withhold solid foods and milk for at least 12 hours prior to medication and for 4 hours afterward.

[45 FR 10333, Feb. 15, 1980]

§ 520.600 Dichlorvos.

(a) *Chemical name.* 2,2-Dichlorovinyl dimethyl phosphate.

(b) [Reserved]

(c) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.180 of this chapter.

(e) *Conditions of use in swine.* (1) It is recommended for the removal and control of sexually mature (adult), sexually immature and/or 4th stage larvae of the whipworm (*Trichuris suis*), nodular worms (*Oesophagostomum* spp.), large round-worm (*Ascaris suum*), and the mature thick stomach worm (*Ascarops strongylina*) occurring in the lumen of the gastrointestinal tract of pigs, boars, and open or bred gilts and sows.

(2) The preparation should be added to the indicated amount of feed as set forth in paragraph (e)(2) of this section and administered shortly after mixing, as follows:

Weight of animal in pounds	Pounds of feed to be mixed with each 0.08 ounce of dichlorvos	Pounds of mixed feed to be administered to each pig as a single treatment	Number of pigs to be treated per 0.08 ounce of dichlorvos
20-30	4	0.33	12
31-40	5	0.56	9
41-60	6	1.00	6
61-80	5	1.00	5
81-100	4	1.00	4
Adult Gilts, Sows, and Boars	16	4.00	4

(3) Do not use this product on animals either simultaneously or within a

few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. The preparation should be mixed thoroughly with the feed on a clean, impervious surface. Do not allow swine access to feed other than that containing the preparation until treatment is complete. Do not treat pigs with signs of scours until these signs subside or are alleviated by proper medication. Resume normal feeding schedule afterwards. Swine may be retreated in 4 to 5 weeks.

(f) *Conditions of use in dogs.* (1) For removal of *Toxocara canis* and *Toxascaris leonina* (roundworms), *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms), and *Trichuris vulpis* (whipworm) residing in the lumen of the gastrointestinal tract.

(2) The drug is in capsule form for direct administration and in pellet form for administration in about one-third of the regular canned dog food ration or in ground meat. Dogs may be treated with any combination of capsules and/or pellets so that the animal receives a single dose equaling 12 to 15 milligrams of the active ingredient per pound of body weight. One-half of the single recommended dosage may be given, and the other half may be administered 8 to 24 hours later. This split dosage schedule should be used in animals which are very old, heavily parasitized, anemic, or otherwise debilitated. The drug should not be used in dogs weighing less than 2 pounds.

(3) In some dogs, efficacy against *Trichurias vulpis* (whipworm) may be erratic. Dogs that do not develop a negative stool for *Trichuris vulpis* ova 10 to 14 days following initial treatment should be re-treated. If a negative stool is not obtained in 10 to 14 days following re-treatment, alternate means of therapy should be considered.

(4) Do not use in dogs infected with *Dirofilaria immitis*.

(5) Do not use with other anthelmintics, taeniocides, antifilarial agents, muscle relaxants, or tranquilizers.

(6) The drug is a cholinesterase inhibitor. Not for use simultaneously or