

§ 520.606

cholinesterase-inhibiting drugs, pesticides, or chemicals.

(6) Do not use in animals under 10 days of age or 1 pound of body weight.

(7) Do not administer to animals showing signs of constipation, mechanical blockage of the intestinal tract, impaired liver function, or recently exposed to or showing signs of infectious disease.

(8) Do not use in dogs or puppies infected with *Dirofilaria immitis*.

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

[40 FR 13838, Mar. 27, 1975, as amended at 48 FR 40704, Sept. 9, 1983; 51 FR 28546, Aug. 8, 1986; 62 FR 35076, June 30, 1997; 64 FR 18571, Apr. 15, 1999]

§ 520.606 Diclazuril.

(a) *Specifications.* Each 100 grams (g) of pellets contain 1.56 g diclazuril.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 milligram (mg) per kilogram (0.45 mg per pound) of body weight in the daily grain ration for 28 days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.

(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.

[72 FR 20943, Apr. 27, 2007]

§ 520.608 Dicloxacillin sodium monohydrate capsules.

(a) *Specifications.* Each capsule contains dicloxacillin sodium monohydrate equivalent to 50, 100, 200, or 500 milligrams of dicloxacillin.

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

(c) *Conditions of use. Dogs*—(1) *Amount.* 5 to 10 milligrams per pound of body weight, three times daily. In severe cases, up to 25 milligrams per pound of body weight three times daily.

(2) *Indications for use.* Treatment of pyoderma (pyogenic dermatitis) due to penicillinase-producing staphylococci sensitive to the drug.

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(3) *Limitations.* For the treatment of dogs only. Continue treatment for 24 to 48 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours before feeding to ensure maximum absorption. Not for use in animals which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37325, Aug. 18, 1992]

§ 520.620 Diethylcarbamazine oral dosage forms.

§ 520.622 Diethylcarbamazine citrate oral dosage forms.

§ 520.622a Diethylcarbamazine citrate tablets.

(a) *Sponsors.* (1) See 015579 in § 510.600(c) of this chapter for use of 50, 200, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(2) See 053501 in § 510.600(c) of this chapter for use of 100, 200, and 300 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs.

(3) See 061623 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(4) See 017030 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(5) See 000081 in § 510.600(c) of this chapter for use of 60, 120, or 180 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(6) See No. 000010 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(b) *Conditions of use*—(1) *Dosage/indications for use.* (i) Three milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) Three milligrams per pound of body weight daily as an aid in the control of ascarid infections (*Toxocara canis*) in dogs.

(iii) Twenty-five to 50 milligrams per pound of body weight as an aid in the treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*).

(2) *Limitations.* Administer orally either pulverized and given in feed or water or directly by mouth. For the treatment of ascarid infections, repeat in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions because of pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start at the beginning of mosquito activity and be continued daily throughout the mosquito season and for approximately a month thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 23230, Apr. 24, 1981, as amended at 46 FR 41038, Aug. 14, 1981; 46 FR 46315, Sept. 18, 1981; 46 FR 61653, Dec. 18, 1981; 47 FR 10805, Mar. 12, 1982; 47 FR 14150, Apr. 2, 1982; 50 FR 41489, Oct. 11, 1985; 50 FR 49372, Dec. 2, 1985; 53 FR 40056, Oct. 13, 1988; 53 FR 40727, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003]

EFFECTIVE DATE NOTE: At 76 FR 17777, Mar. 31, 2011, § 520.622a was amended by removing and reserving paragraph (a)(1); in paragraph (a)(5), removing “000081” and in its place add “No. 000061”; and revising paragraph (b)(2), effective April 11, 2011. For the convenience of the user, the revised text is set forth as follows:

§ 520.622a Diethylcarbamazine citrate tablets.

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(b) * * *

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

§ 520.622b Diethylcarbamazine citrate syrup.

(a)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

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

(3) *Conditions of use.* (i) The drug is indicated for use in dogs for the prevention of infection with *Dirofilaria immitis* and *T. canis* and *T. leonina*. It is also indicated for treatment of ascarid infections of *T. canis* and *T. leonina* in dogs and *T. cati* in cats.

(ii) For prevention of heartworm and ascarid infections in dogs, the drug may be added to the daily diet at a dosage rate of 3.0 milligrams per pound of body weight per day or given directly by mouth at the same dosage rate. For treatment of ascarid infections in dogs and cats, the drug is administered at a dosage level of 25 to 50 milligrams per pound of body weight preferably administered immediately after feeding.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administration of this drug.

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

(b)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsors.* (i) See No. 017030 for use as in paragraphs (b)(3)(ii)(a) and (b)(3)(ii)(c) of this section.

(ii) See No. 017030 for use as in paragraphs (b)(3)(ii) (a) and (c) of this section.

(3) *Conditions of use*—(i) *Amount.* 3 milligrams per pound of body weight per day for prevention of heartworm disease and as an aid in control of large roundworms; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(ii) *Indications for use.* (a) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.