

**§ 520.763**

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

[72 FR 263, Jan. 4, 2007]

**§ 520.763 Dithiazanine iodide oral dosage forms.**

**§ 520.763a Dithiazanine iodide tablets.**

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl - 2 - benzothiazolinyldiene) - 1,3 - pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

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

(d) *Conditions of use.* (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms ( <i>Toxocara canis</i> , <i>Toxascaris leonina</i> ) .....	10	3-5
Hookworms ( <i>Ancylostoma caninum</i> , <i>Uncinaria stenocephala</i> ) .....	10	7
Whipworms ( <i>Trichuris vulpis</i> ) .....	10	
Strongyloides ( <i>Strongyloides canis</i> , <i>Strongyloides stercoralis</i> ) .....	10	10-12
Heartworm microfilariae ( <i>Dirofilaria immitis</i> ) .....	3-5	7-10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

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

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111

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of this chapter, but may require bio-equivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

**§ 520.763b Dithiazanine iodide powder.**

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinyldiene)-1,3-pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

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

(d) *Conditions of use.* (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms ( <i>Toxocara canis</i> , <i>Toxascaris leonina</i> ) .....	10	3-5
Hookworms ( <i>Ancylostoma caninum</i> , <i>Uncinaria stenocephala</i> ) .....	10	7
Whipworms ( <i>Trichuris vulpis</i> ) .....	10	7
Strongyloides ( <i>Strongyloides canis</i> , <i>Strongyloides stercoralis</i> ) .....	10	10-12
Heartworm microfilariae ( <i>Dirofilaria immitis</i> ) .....	3-5	7-10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

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

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been 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.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

**§ 520.763c Dithiazanine iodide and piperazine citrate suspension.**

(a) *Specifications.* Each milliliter of the drug contains 69 milligrams of dithiazanine iodide and 83 milligrams of piperazine base (as piperazine citrate).

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use are NAS/NRC reviewed and found 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.

(d) *Conditions of use*—(1) *Amount.* 1 ounce (30 milliliters) per 100 pounds of body weight for the first 500 pounds;  $\frac{3}{4}$  ounce for each 100 pounds thereafter, up to 1,200 pounds;  $10\frac{1}{4}$  ounces to animals over 1,200 pounds.

(2) *Indications for use.* For control of large roundworms, *Parascaris equorum*; small strongyles; large strongyles, *Strongylus vulgaris*; and pinworms, *Oxyuris equi*.

(3) *Limitations.* Administer by drench or mixed with the daily ration as a single dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."

[47 FR 52696, Nov. 23, 1982, as amended at 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

**§ 520.784 Doxylamine succinate tablets.**

(a) *Specifications.* The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

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

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.<sup>1</sup>

(2) It is administered orally to horses at a dosage level of 1 to 2 milligrams per pound of body weight per day divided into 3 or 4 equal doses. It is administered orally to dogs and cats at a dosage level of 2 to 3 milligrams per pound of body weight per day divided into 3 or 4 equal doses.<sup>1</sup>

(3) Not for use in horses intended for food.<sup>1</sup>

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

**§ 520.804 Enalapril tablets.**

(a) *Specifications.* Each tablet contains either 1.0, 2.5, 5.0, 10.0, or 20.0 milligrams of enalapril maleate.

(b) *Sponsor.* See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.5 to 1.0 milligram of enalapril maleate per kilogram of body weight per day.

(ii) *Indications for use.* Treatment of mild, moderate, and severe (modified New York Heart Association Class II, III, IV) heart failure in dogs.

(iii) *Limitations.* Use 0.5 milligram per kilogram once daily. In the absence of adequate clinical response within a 2-week period, use may be increased to twice daily (a total of 1.0 milligram per kilogram). Enalapril maleate is administered as conjunctive therapy with furosemide and digoxin in the treatment of dilated cardiomyopathy and furosemide with or without digoxin in the treatment of chronic valvular disease. The safety of enalapril for use in breeding dogs has not been established. Use in pregnant bitches is not recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

<sup>1</sup>These 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.