

§ 520.1204

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

(c) *Conditions of use in dogs*—(1) *Amount*. Administer tablets to provide 6 µg per kilogram (/kg) ivermectin, 100 mg/kg fenbendazole, and 5 mg/kg praziquantel.

(2) *Indications for use*. For the treatment and control of adult *Toxocara canis* (roundworm), *Ancylostoma caninum* (hookworm), *Trichuris vulpis* (whipworm), and *Dipylidium caninum* (tapeworm), and for the prevention of heartworm disease caused by *Dirofilaria immitis* in adult dogs.

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

[73 FR 33692, June 13, 2008, as amended at 74 FR 61516, Nov. 25, 2009]

§ 520.1204 Kanamycin, bismuth subcarbonate, activated attapulgite.

(a) *Specifications*—(1) Each 5 milliliters (mL) of suspension contains 100 milligrams (mg) kanamycin (as the sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite (aluminum magnesium silicate).

(2) Each tablet contains 100 mg kanamycin (as the sulfate), 250 mg bismuth subcarbonate, and 500 mg activated attapulgite.

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

(c) *Conditions of use in dogs*—(1) *Amount*. 5 mL of suspension or 1 tablet per 20 pounds body weight every 8 hours. Maximum dose: 5 mL of suspension or 3 tablets every 8 hours. Dogs under 10 pounds: 2.5 mL of suspension or ½ tablet every 8 hours. A recommended initial loading dose should be twice the amount of a single dose.

(2) *Indications for use*. For the treatment of bacterial enteritis caused by organisms susceptible to kanamycin and the symptomatic relief of the associated diarrhea.

(3) *Limitations*. 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 53 FR 27851, July 25, 1988; 56 FR 8710, Mar. 1, 1991; 64 FR 403, Jan. 5, 1999; 71 FR 43968, Aug. 3, 2006]

21 CFR Ch. I (4–1–13 Edition)

§ 520.1242 Levamisole.

§ 520.1242a Levamisole powder.

(a) *Specifications*. Each package of powder contains 9.075, 11.7, 18.15, 46.8, 362.7, or 544.5 grams (g) levamisole hydrochloride.

(b) *Sponsors*. See sponsors in § 510.600(c) for use as follows:

(1) No. 000061 for use of 46.8- and 544.5-g packages as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section; for 11.7-, 46.8-, and 544.5-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for an 18.15-g package as in paragraph (e)(3) of this section.

(2) No. 053501 for use of a 46.8-g package as in paragraph (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section; for 11.7- and 46.8-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section; and for 9.075- and 18.15-g packages as in paragraph (e)(3) of this section.

(3) No. 057561 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) and (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section.

(4) No. 059130 for use of 46.8-, 362.7-, and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(B), (e)(1)(iii), (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for use of an 18.15-g package as in paragraph (e)(3) of this section.

(c) *Related tolerances*. See § 556.350 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use*. It is used as an anthelmintic as follows:

(1) *Cattle*—(i) *Amount*. 8 milligrams per kilogram (mg/kg) body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*); intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus placei*, *Ostertagia ostertagi*, *Trichostrongylus axei*); intestinal worms (*T. longispicularis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus*

spathiger, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*); and lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations*. Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult your veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount*. 8 mg/kg body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*); intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*); intestinal worms (*Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*), and lungworms (*Dictyocaulus filaria*).

(iii) *Limitations*. Do not slaughter for food within 72 hours of treatment. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult veterinarian before using in severely debilitated animals.

(3) *Swine*—(i) *Amount*. 8 mg/kg body weight in drinking water.

(ii) *Indications for use*. Effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus* spp.).

(iii) *Limitations*. Do not administer within 72 hours of slaughter for food. Pigs maintained under conditions of constant exposure to worms may require retreatment within 4 to 5 weeks after the first treatment. Consult your veterinarian before administering to sick swine.

[69 FR 9753, Mar. 2, 2004, as amended at 69 FR 33839, June 17, 2004; 70 FR 2353, Jan. 13, 2005; 77 FR 28253, May 14, 2012]

§ 520.1242b Levamisole hydrochloride tablet or oblet (bolus).

(a) *Chemical name*. (-)-2,3,5,6-Tetrahydro-6-phenylimidazo [2,1-*b*] thiazole monohydrochloride.

(b) *Specifications*. Assay of not less than 98 percent by nonaqueous titration with 0.1 N potassium isopropoxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) *Sponsor*. See Nos. 000061 and 053501 in § 510.600(c) of this chapter.

(d) *Required labeling*. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(e) *Related tolerances*. See § 556.350 of this chapter.

(f) *Conditions of use*. (1) It is used in an oblet for cattle as follows:

(i) *Amount*. 2.19 grams per oblet.

(ii) *Indications for use*. Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations*. Administer as a single dose as follows: 250 to 450 pounds, ½ oblet; 450 to 750 pounds, 1 oblet; and 750 to 1,050 pounds, 1½ oblets; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; not for use in dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) It is used in a tablet for sheep as follows:

(i) *Amount*. 0.184 gram per tablet.

(ii) *Indications for use*. Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(iii) *Limitations*. Administer one tablet for each 50 pounds of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do