Food and Drug Administration, HHS

§ 520.1242b

(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:

(i) 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, Chabertia); and lungworms (Dictyocaulus).

(B) Effective against the following adult nematode infections: Stomach worms (Haemonchus contortus, Trichostrongylus axei, Teladorsagia circumcincta); intestinal worms (T. longispicularis, 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 your veterinarian before using in severely debilitated animals.

(ii) 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 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 72 hours of treatment. 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.


§ 520.1242b Levamisole hydrochloride tablet or oblet (bolus)

(a) Chemical name. (-)-2,3,5,6-Tetrahydro-6-phenylimidazo [2,1-b] thiazole monohydrochloride.
§ 520.1242c Levamisole hydrochloride and piperazine dihydrochloride.

(a) Specifications. (1) The drug is an aqueous solution which contains in each fluid ounce 0.36 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 3.98 grams of piperazine base.

(2) The drug is a soluble powder which when reconstituted with water contains in each fluid ounce 0.45 gram of levamisole hydrochloride and piperazine dihydrochloride equivalent to 5.0 grams of piperazine base.

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

(c) [Reserved]

(d) Conditions of use. It is used as a drench for horses as follows:

(1) Indications for use. An anthelmintic effective against infections of large strongyles (Strongylus vulgaris, S. edentatus), small strongyles (Cylicocercus spp., Cylicocylclus spp., Cylicodontophorus spp., Cylicostephanus spp., Cylicotetrapedon spp.), ascarids (Parascaris equorum), and pinworms (Oxyuris equi).

(2) Limitations. Aqueous solution: administer by stomach tube or drench 1 fluid ounce per 100 pounds of body weight. Reconstituted soluble powder: administer by stomach tube 1 fluid ounce per 125 pounds of body weight. If reinfestation occurs, re-treat animals at 6- to 8-week intervals. Do not treat animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.