

§ 520.1242b

21 CFR Ch. I (4-1-03 Edition)

Consult your veterinarian before administering to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food.

[40 FR 13838, Mar. 27, 1975, as amended at 43 FR 11176, Mar. 17, 1978; 44 FR 59508, Oct. 16, 1979; 44 FR 72586, Dec. 14, 1979; 46 FR 25085, May 5, 1981; 52 FR 20598, June 2, 1987; 54 FR 18280, Apr. 28, 1989; 62 FR 61625, Nov. 19, 1997; 63 FR 59713, Nov. 5, 1998; 67 FR 63055, Oct. 10, 2002; 68 FR 4916, Jan. 31, 2003]

§ 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 not slaughter for food within 72 hours of treatment; consult a veterinarian before using in severely debilitated animals.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 59507, Oct. 16, 1979; 62 FR 61625, Nov. 19, 1997; 67 FR 63055, Oct. 10, 2002]

§ 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 reinfection occurs, re-treat animals at