

§520.1242g

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

(*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations*. Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not administer to cattle within 6 days of slaughter for food; do not administer to dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) *Breeding swine*—(i) *Amount*. Eight milligrams per kilogram of body weight (3.6 milligrams per pound) as a single oral dose.

(ii) *Conditions of use*. For treating breeding swine infected with the following nematodes: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), and kidney worms (*Stephanurus dentatus*).

(iii) *Limitations*. May require retreatment in 4 to 5 weeks. Do not use within 11 days of slaughter for food. Consult your veterinarian for assistance before using in severely debilitated animals and in the diagnosis, treatment, and control of parasitism.

[47 FR 22517, May 25, 1982; 47 FR 30242, July 13, 1982, as amended at 48 FR 11429, Mar. 18, 1983; 51 FR 29215, Aug. 15, 1986; 67 FR 63055, Oct. 10, 2002]

§520.1242g Levamisole resinate and famphur paste.

(a) *Chemical name of famphur*. *O*, *O*-Dimethyl *O*-[*p*-(dimethylsulfamoyl)phenyl] phosphorothioate.

(b) *Specifications*. The drug is a paste containing 11.6 percent levamisole resinate (50 percent potency) and 23.6 percent famphur.

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

(d) *Special considerations*. Do not use any cholinesterase-inhibiting drugs, pesticides, insecticides, or chemicals on cattle simultaneously or within a few days before or after treatment with this product.

(e) *Related tolerances*. See §556.350 of this chapter for levamisole and §556.273 of this chapter for famphur.

(f) *Conditions of use in cattle*—(1) *Amount*. 8 milligrams of levamisole hydrochloride (equivalent) and 30 milligrams of famphur activity per kilogram of body weight.

(2) *Indications for use*. For treatment of cattle infected with the following parasites: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), lungworms (*Dictyocaulus*), cattle grubs (*Hypoderma*), biting lice (*Bovicola*), and sucking lice (*Linognathus*, *Solenoptes*).

(3) *Limitations*. Drug is not effective against lice eggs. Conditions of constant helminth and ectoparasitic exposure may require retreatment within 2 to 4 weeks after first treatment. Do not administer to cattle within 19 days of slaughter. Do not administer to dairy animals of breeding age. Do not use in calves less than 3 months old, or in debilitated animals. Do not treat Brahman bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 23757, June 24, 1988, as amended at 54 FR 1353, Jan. 13, 1989; 57 FR 7652, Mar. 4, 1992; 62 FR 55160, Oct. 23, 1997; 62 FR 61625, Nov. 19, 1997]

§520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.

§520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.

(a) *Specifications*. The sirup contains lincomycin hydrochloride equivalent to either 25 milligrams or 50 milligrams of lincomycin.

(b) *Sponsor*. See No. 000009 in §510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is indicated in infections caused by gram-positive organisms which are sensitive to its action, particularly streptococci and staphylococci.

(2) It is administered orally to dogs and cats at a dosage level of 10 mgs per pound of body weight every 12 hours, or 7 mgs per pound of body weight every 8 hours. Treatment may be continued for

periods as long as 12 days if clinical judgment indicates.

(3) 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 44 FR 7130, Feb. 6, 1979; 64 FR 403, Jan. 5, 1999]

§ 520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.

(a) *Specifications.* The spectinomycin sulfate tetrahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces spectabilis* or the same antibiotic substance produced by any other means. The quantity of total antibiotic activity cited in this section refers to the equivalent weight of the base activity of the drugs. Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate are present in the drug in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.600 and 556.360 of this chapter.

(d) *Conditions of use.* (1) It is administered in the drinking water of chickens up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

(2) For aid in the control of these conditions it is administered in the drinking water at a level of 2 grams of antibiotic activity per gallon of water as the sole source of water for the first 5 to 7 days of life.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 1891, Jan. 13, 1976; 64 FR 403, Jan. 5, 1999]

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications.* Each gram of soluble powder contains lincomycin hydrochloride equivalent to 0.4 grams of lincomycin.

(b) *Sponsors.* See Nos. 000009, 046573, 051259, and 059130 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Tolerances.* See § 556.360 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount.* 250 milligrams per gallon of drinking water to provide 3.8 milligrams per pound of body weight per day.

(ii) *Indications for use.* For the treatment of swine dysentery (bloody scours).

(iii) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. The safety of lincomycin has not been demonstrated in pregnant swine or swine intended for breeding. For No. 051259: Do not slaughter swine for 6 days following last treatment.

(2) *Chickens*—(i) *Amount.* 64 milligrams per gallon of drinking water.

(ii) *Indications for use.* For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens.

(iii) *Limitations.* Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens.

[48 FR 3966, Jan. 28, 1983, as amended at 55 FR 3209, Jan. 31, 1990; 60 FR 14217, Mar. 16, 1995; 62 FR 65020, Dec. 10, 1997; 64 FR 13341, Mar. 18, 1999; 64 FR 13508, Mar. 19, 1999; 64 FR 66382, Nov. 26, 1999; 65 FR 10705, Feb. 29, 2000; 67 FR 17284, Apr. 10, 2002; 67 FR 71819, Dec. 3, 2002; 67 FR 78356, Dec. 24, 2002; 68 FR 3817, Jan. 27, 2003]

§ 520.1284 Sodium liothyronine tablets.

(a) *Specifications.* Sodium liothyronine tablets consist of tablets intended for oral administration which contain liothyronine at 60 or 120 micrograms per tablet, as the sodium salt.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.