Food and Drug Administration, HHS

§ 520.1195 Ivermectin liquid.

(a) Specifications.—(1) Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter.

§ 520.1194 Ivermectin meal.

(a) Specifications. Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) Sponsor. See No. 017135 in § 510.600(c) of this chapter.

(c) Special considerations. See § 500.25 of this chapter.

(d) Conditions of use in horses.—(1) Amount. Administer 136 micrograms (mcg) ivermectin per pound (lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) Indications for use. For treatment and control of Large Strongyles (adults): Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), S. equinus, Triodontophorus spp. including T. brevicauda and T. serratus, and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): Coronoclycus spp. including C. coronatus, C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum, Cylicoclycus spp. including C. insigne, C. leptostomum, C. nassatus, and C. brevicapsulatus, Cyclicodontophorus spp., Cyclicostephanus spp. including C. calicatus, C. goldi, C. longibursatus, and C. minutus, and Petrovinema pocalatum; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae): Parascaris equorum; Hairworms (adults): Trichostrongylus axei; Large Mouth Stomach Worms (adults): Habronema muscae; Bots (oral and gastric stages): Gasterophilus spp. including G. intestinalis and G. nasalis; Lungworms (adults and fourth-stage larvae): Dictyocaulus arnfieldi; Intestinal Threadworms (adults): Strongyloides westeri; Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.

Limitations. Do not use in horses intended for human consumption.

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(c) Related tolerances. See §556.344 of this chapter.

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

(e) Conditions of use.—(1) Horses—(i) Amount. 200 micrograms (mcg) per kilogram (kg) of body weight as a single dose by stomach tube or as an oral drench.

(ii) Indications for use. For treatment and control of:

(A) Large Strongyles (adults): Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), S. equinus, Triodontophorus spp. including T. brevicauda and T. serratus, and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): Coronocyclus spp. including C. coronatus, C. labratus, and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum, Cylcocyclus spp. including C. insigne, C. leptostomum, C. nassatus, and C. brevicaudatus, Cylicodontophorus spp., Cylicostephanus spp. including C. calicatus, C. goldi, C. longibursatus, and C. minutus, and Petrovinema poculatum; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth-stage larvae); Oxyuris equi; Ascarids (adults and fourth-stage larvae); Firmicystis buse utilities (adults only), Habronema muscae (adults only), Dictyocaulus arnfieldi; Intestinal threadworms (Strongyloides westeri (adult)); Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; and Dermatitis caused by neck threadworm microfilariae (Onchocerca sp.).

(iii) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Sheep—(i) Amount. 200 mcg/kg (3 mL/26 pounds) of body weight as a single dose oral drench.

(ii) Indications for use. For treatment and control of the adult and fourth-stage larvae of gastrointestinal roundworms (Haemonchus contortus, H. placei (adults only), Ostertagia circumcincta, Trichostrongylus axei, T. colubriformis, Cooperia oncophora (adults only), C. curticei, Oesophagostomum columbianum, O. venulosum (adults only), Nematodirus battus, N. pathiger, S. papillosus (adults only), Chabertia ovina (adult only), Trichostrongylus axei (adults only)); lungworms (D. filaria); and all larval stages of the nasal bot Oestrus ovis.

(iii) Limitations. For use in sheep only. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Do not treat sheep within 11 days of slaughter.


§520.1196 Ivermectin and pyrantel pamoate chewable tablets.

(a) Specifications. Each chewable tablet contains either 68 micrograms (µg) of ivermectin and 57 milligrams (mg) of pyrantel (as pamoate salt), or 136 µg and 114 mg, or 272 µg and 227 mg, respectively.

(b) Sponsors. See Nos. 050604, 051311, and 063604 in §510.600(c) of this chapter.