§ 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.

(c) Conditions of use—(1) Dogs—(1) Amount. A minimum of 6 μg of

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(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): Coronocyclex spp. including C. coronatus, C. labiatus, and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum,

Cyclocyclus spp. including C. insigne, C. leptostomum, C. nassatus, and C. brevicaudatus, Cylicodontophorus spp., Cyclicostephanus spp. including C. calicatus, C. goldi, C. longibursatus, and C. minuta, and Petrovinema poculatum;

Small Strongyles (fourth-stage larvae): Pinworms (adults and fourth stage larvae): Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae): Parasacificus equorum; Hairyworms (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; and Dermatitis caused by neck threadworm microfilariae (Onchocerca spp.).

(B) Large Strongyles (Strongylus equinus (adult), S. vulgaris (adult and arterial larval stages), S. endentatus (adult and migrating tissue stages), Triodontophorus spp. (adult)); Small Strongyles including those resistant to some benzimidazole class compounds (Cyathostomum spp. (adult and fourth-stage larvae), Cylicocyclus spp., Cylicodontophorus spp., Cyclicostephanus spp.); Pinworms (Oxyuris equi (adult and fourth-stage larvae)); Ascarids (Parascaris equorum (adult and third- and fourth-stage larvae)); Hairworms (Trichostrongylus axei(adult)); Large mouth Stomach Worms (Habronema muscae (adult)); Stomach Bots (Gastrophilus spp. (oral and gastric stages)); Lungworms (Dictyocaulus arnfieldi (adult and fourth-stage larvae)); 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 spp.).

(iv) 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. spathiger, S. papillosus (adults only), Chabertia ovina (adult only), Trichuris ovis (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.
§ 520.1197 Ivermectin and praziquantel paste.

(a) Specifications. Each milliliter (mg) of paste contains:
   (1) 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.
   (2) 0.0187 mg (1.87 percent) ivermectin and 0.1403 mg (14.03 percent) praziquantel.

(b) Sponsor. See sponsors in §510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 050604 for use of product described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i), (d)(2)(i) and (d)(3) of this section.

(2) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii), (d)(2)(ii), and (d)(3) of this section.

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

(d) Conditions of use in horses—(1) Amount—(i) 200 micrograms (mcg) per kilogram (lb) ivermectin (91 mcg per pound (lb)) and 1 mg/kg praziquantel (454 mcg/lb) body weight.
   (ii) 200 mcg/kg ivermectin (91 mcg/lb) and 1.5 mg/kg praziquantel (681 mcg/lb) body weight.

(2) Indications for use. For treatment and control of:
   (i) Tapeworms—Anoplocephala perfoliata; 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)—Coronocyclops spp. including C. coronatus, C. labiatus, and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum,