Food and Drug Administration, HHS

§ 520.1197 Ivermectin sustained-release bolus.

(a) Specifications. Each sustained-release bolus contains 1.72 grams of ivermectin.

(b) Sponsor. See No. 050604 in §510.600(c) of this chapter.

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

(d) Conditions of use in ruminating calves—(1) Amount. Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.

(2) Indications. For treatment and control, throughout the grazing season (approximately 130 days), of gastrointestinal roundworms Haemonchus placei, Ostertagia ostertagi (including inhibited fourth-stage larvae), Trichostrongylus axei, T. colubriformis, Cooperia spp., Nematodirus helvetianus, Bunostomum phlebotomum, Oesophagostomum radiatum; lungworms Dictyocaulus viviparus; grubs Hypoderma spp.; sucking lice Linognathus vituli, Solenopotes capillatus; mange mites Psoroptes ovis, Sarcoptes scabiei, and ticks Amblyomma americanum.

(3) Limitations. The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.


§ 520.1198 Ivermectin and praziquantel paste.

(a) Specifications. Each milligram (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) Sponsors. 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.

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

(d) Conditions of use in horses—(1) Amount—(i) 200 micrograms (mcg) per kilogram (/kg) 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)—Coronocyclus spp. including C. coronatus, C. labiatus, and C.
§ 520.1199 Ivermectin, pyrantel, and praziquantel tablets.

(a) Specifications. Each chewable tablet contains:

(1) 34 micrograms (mcg) ivermectin, 28.5 milligrams (mg) pyrantel pamoate, and 28.5 mg praziquantel;

(2) 68 mcg ivermectin, 57 mg pyrantel pamoate, and 57 mg praziquantel;

(3) 136 mcg ivermectin, 114 mg pyrantel pamoate, and 114 mg praziquantel; or

(4) 272 mcg ivermectin, 228 mg pyrantel pamoate, and 228 mg praziquantel.

(b) Sponsors. See No. 051311 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Administer monthly according to body weight as follows:

(i) 6 to 12 lb: one tablet as described in paragraph (a)(1) of this section.

(ii) 12.1 to 25 lb: one tablet as described in paragraph (a)(2) of this section.

(iii) 25.1 to 50 lb: one tablet as described in paragraph (a)(2) of this section.

(iv) 50.1 to 100 lb: one tablet as described in paragraph (a)(3) of this section.

(v) Greater than 100 lb: use the appropriate combination of tablets.

(2) Indications for use. Prevents canine heartworm disease by eliminating the tissue stage of heartworm larvae (Dirofilaria immitis) for 1 month (30 days) after infection and for the treatment and control of roundworm (Toxocara canis, Toxascaris leonina), hookworm (Ancylostoma caninum, Uncinia stenocephala, Ancylostoma braziliense) and tapeworm (Dipylidium caninum, Taenia pisiformis) infections.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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§ 520.1200 Ivermectin, fenbendazole, and praziquantel tablets.

(a) Specifications. Each chewable tablet contains either:

(1) 68 micrograms (μg) ivermectin, 1.134 grams fenbendazole, and 57 milligrams (mg) praziquantel; or

(2) 27 μg ivermectin, 454 mg fenbendazole, and 23 mg praziquantel.