§ 522.1192  Ivermectin.

(a) Specifications—(1) Each milliliter (mL) of solution contains 20 milligrams (mg) ivermectin.
(2) Each mL of solution contains 10 mg ivermectin.
(3) Each mL of solution contains 2.7 mg ivermectin.

(b) Sponsors. See sponsors in §510.600(c) of this chapter for use as in paragraph (e) of this section.

(c) Indications for use. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (Haemonchus placei, Ostertagia ostertagi (including inhibited larvae), O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus (adults only), N. pathiger (adults only), Bunostomum phlebotomum); lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); grubs (parasitic stages) (Hypoderma bolii, H. lineatum); sucking lice (Linognathus setulosus); stomach worms (adult) (Habronema muscae), neck threadworms (microfilariae) (Onchocerca sp.), and stomach bots (Gastrophilus spp.).

(d) Special considerations—(1) See §500.25 of this chapter.

(2) Labeling shall bear the following precaution: ‘‘This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.’’

(e) Conditions of use—(1) Horses—(i) Amount. 200 micrograms per kilogram (µg/kg) of body weight by intramuscular injection.

(2) Cattle—(i) Amount. 200 µg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of large strongyles (adult) (Strongylus vulgaris, S. edentatus, Tridontophorus spp.), small strongyles (adult and fourth stage larvae) (Cyathostomum spp., Cyclicocyclus spp., Cyclicostephanus spp.), pinworms (adult and fourth-stage larvae) (Firstostrongylus axei), large roundworms (adult) (Parascaris equorum), hairworms (adult) (Trichostrongylus axei), large mouth stomach worms (adult) (Habronema muscae), neck threadworms (microfilariae) (Onchocerca sp.), and stomach bots (Gastrophilus spp.).

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

(3) Cattle—(ii) Indications for use. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (Haemonchus placei, Ostertagia ostertagi (including inhibited larvae), O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus (adults only), N. pathiger (adults only), Bunostomum phlebotomum); lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); grubs (parasitic stages) (Hypoderma bolii, H. lineatum); sucking lice (Linognathus setulosus); stomach worms (adult) (Habronema muscae), neck threadworms (microfilariae) (Onchocerca sp.), and stomach bots (Gastrophilus spp.).

(4) Cattle—(i) Amount. 200 µg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of large strongyles (adult) (Strongylus vulgaris, S. edentatus, Tridontophorus spp.), small strongyles (adult and fourth stage larvae) (Cyathostomum spp., Cyclicocyclus spp., Cyclicostephanus spp.), pinworms (adult and fourth-stage larvae) (Firstostrongylus axei), large roundworms (adult) (Parascaris equorum), hairworms (adult) (Trichostrongylus axei), large mouth stomach worms (adult) (Habronema muscae), neck threadworms (microfilariae) (Onchocerca sp.), and stomach bots (Gastrophilus spp.).

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

(5) Cattle—(ii) Indications for use. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (Haemonchus placei, Ostertagia ostertagi (including inhibited larvae), O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus (adults only), N. pathiger (adults only), Bunostomum phlebotomum); lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); grubs (parasitic stages) (Hypoderma bolii, H. lineatum); sucking lice (Linognathus setulosus); stomach worms (adult) (Habronema muscae), neck threadworms (microfilariae) (Onchocerca sp.), and stomach bots (Gastrophilus spp.).

(6) Cattle—(i) Amount. 200 µg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of large strongyles (adult) (Strongylus vulgaris, S. edentatus, Tridontophorus spp.), small strongyles (adult and fourth stage larvae) (Cyathostomum spp., Cyclicocyclus spp., Cyclicostephanus spp.), pinworms (adult and fourth-stage larvae) (Firstostrongylus axei), large roundworms (adult) (Parascaris equorum), hairworms (adult) (Trichostrongylus axei), large mouth stomach worms (adult) (Habronema muscae), neck threadworms (microfilariae) (Onchocerca sp.), and stomach bots (Gastrophilus spp.).

(iii) Limitations. Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
(iii) Limitations. Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(3) Swine—(i) Amount. 300 μg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, Ascaris suum; red stomach worm, Hystonglylus ruditus; nodular worm, Oesophagostomum spp.; threadworm, Strongyloides ransomi (adults only)); somatic roundworm larvae (threadworm, S. ransomi (somatic larvae)); lungworms (Metastrongylus spp. (adults only)); lice (H. suis); and mites (S. scabiei var. suis).

(iii) Limitations. Do not treat swine within 18 days of slaughter.

(4) American bison—(i) Amount. 200 μg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of grubs (H. bovis).

(iii) Limitations. Do not slaughter within 56 days of last treatment.

(5) Reindeer—(i) Amount. 200 μg/kg of body weight by subcutaneous injection.

(ii) Indications for use. For the treatment and control of warbles (Oedemagena tarandi).

(iii) Limitations. Do not treat reindeer within 56 days of slaughter.

(6) Ranch-raised foxes—(i) Amount. 200 μg/kg of body weight by subcutaneous injection. Repeat in 3 weeks.

(ii) Indications for use. For treatment and control of ear mites (Otodectes cynotis).

§ 522.1204 Kanamycin sulfate injection.

(a) Specifications. Each milliliter (mL) of solution contains 10 milligrams (mg) (1 percent) ivermectin and 100 mg (10 percent) clorsulon.

(b) Sponsors. See Nos. 000856 in §510.600(c) of this chapter for use as in paragraph (e) of this section.

(c) Related tolerances. See §§556.163 and 556.344 of this chapter.

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

(e) Conditions of use in cattle—(1) Amount. Administer 1 mL (10 mg ivermectin and 100 mg clorsulon) per 50 kilograms (110 pounds) by subcutaneous injection.

(2) Indications for use. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (Haemonchus placei, Ostertagia ostertagi (including inhibited larvae), O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus (adults only), N. spathiger (adults only), Bunostomum phlebotomum; lungworms (adults and fourth-stage larvae) (Dictyocaulus viviparus); liver flukes (adults only) (Fasciola hepatica); grubs (parasitic stages) (Hyphodera bovis, H. lineatum); lice (Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus); mites (Psoroptes ovis (syn. P. commune var. bovis), Sarcoptes scabiei var. bovis); and for control of infections of D. viviparus and O. radiatum for 28 days after treatment; O. ostertagi, T. axei, and C. punctata for 21 days after treatment; and H. placei and C. oncophora for 14 days after treatment.

(3) Limitations. For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

§ 522.1193 Ivermectin and clorsulon.

(a) Specifications. Each milliliter (mL) of solution contains 10 milligrams (mg) (1 percent) ivermectin and 100 mg (10 percent) clorsulon.

(b) Sponsors. See Nos. 050604 and 050529 in §510.600(c) of this chapter for use as in paragraph (e) of this section.