Food and Drug Administration, HHS

§ 524.770 Doramectin.

(a) Specifications. Each milliliter (mL) of solution contains 5 milligrams (mg) doramectin.

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

(c) Conditions of use in cattle—(1) Amount. Administer topically as a single dose 0.5 mg (1 mL) per kilogram (1 mL per 22 pounds) body weight.

(2) Indications for use. For treatment and control of gastrointestinal roundworms: Ostertagia ostertagi (adults and fourth-stage larvae), Ostertagia ostertagi (inhibited fourth-stage larvae), Ostertagia lyrata (adults), Haemonchus placei (adults and fourth-stage larvae), Trichostrongylus axei (adults and fourth-stage larvae), Trichostrongylus colubriformis (adults

§ 524.660b Dimethyl sulfoxide ophthalmic and topical dosage forms.

§ 524.660a Dimethyl sulfoxide solution.

(a) Specifications. Dimethyl sulfoxide solution contains 90 percent of dimethyl sulfoxide and 10 percent of water.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use. (1) It is used or intended for use as a topical application to reduce acute swelling due to trauma:

(i) In horses administered 2 or 3 times daily in an amount not to exceed 100 milliliters per day. Total duration of therapy should not exceed 30 days.

(ii) In dogs administered 3 or 4 times daily in an amount not to exceed 20 milliliters per day. Total duration of therapy should not exceed 14 days.

(2) Not for use in horses and dogs intended for breeding purposes or in horses slaughtered for food. Other topical medications should only be used when the dimethyl sulfoxide treated area is thoroughly dry. Do not administer by any other route.

(3) For use by or on the order of a licensed veterinarian.


§ 524.660b Dimethyl sulfoxide ophthalmic and topical dosage forms.

(a) Specifications. Dimethyl sulfoxide gel, veterinary contains 90 percent dimethyl sulfoxide in an aqueous gel.

(b) Sponsor. See No. 000856 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Indications for use. For use on horses and dogs as a topical application to reduce acute swelling due to trauma.

(2) Amount—(i) Horses. Administer 2 or 3 times daily in an amount not to exceed 100 grams per day. Total duration of therapy should not exceed 30 days.

(ii) Dogs. Administer 3 or 4 times daily in an amount not to exceed 20 grams per day. Total duration of therapy should not exceed 14 days.

(3) Limitations. Do not use in horses and dogs intended for breeding purposes or in horses slaughtered for food. Restricted to topical use on horses and dogs only. Due to rapid penetrating ability of dimethyl sulfoxide, rubber gloves should be worn when applying the drug. No other medications should be present on the skin prior to application of the drug. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.775 Emodepside and praziquantel.

(a) Specifications. Each milliliter contains 21.4 milligrams of emodepside and 5.45 milligrams of praziquantel.

(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(c) Conditions of use in cats—(1) Amount. The recommended minimum dose for cats is 1.36 mg/pound (lb) (3 mg/kilogram (kg)) emodepside and 5.45 mg/lb (12 mg/kg) praziquantel applied as a single topical dose.

(2) Indications for use. For the treatment and control of hookworm infections caused by *Ancylostoma tubaeforme* (adults, immature adults, and fourth stage larvae), roundworm infections caused by *Toxocara cati* (adults and fourth stage larvae), and tapeworm infections caused by *Dipylidium caninum* (adults) and *Taenia taeniaeformis* (adults).

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

[72 FR 42991, Aug. 2, 2007]

§ 524.802 Enrofloxacin, silver sulfadiazine emulsion.

(a) Specifications. Each milliliter contains 5 milligrams (mg) enrofloxacin and 10 mg silver sulfadiazine.

(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(c) Conditions of use—Dogs—(1) Amount. 5 to 10 drops for dogs weighing 35 pounds (lb) or less and 10 to 15 drops for dogs weighing more than 35 lb; applied twice daily for up to 14 days.

(2) Indications for use. For the treatment of otitis externa in dogs.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[65 FR 66620, Nov. 7, 2000]

§ 524.814 Eprinomectin.

(a) Specifications. Each milliliter contains 5 milligrams of eprinomectin.

(b) Sponsor. See No. 000006 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.227 of this chapter.

(d) Conditions of use—(1) Amount. One milliliter (5 milligrams) per 10 kilograms of body weight (500 micrograms per kilogram).


(3) Limitations. Do not use in food-producing animals.


§ 524.775 Emodipside and praziquantel.

(a) Specifications. Each milliliter solution contains 21.4 milligrams (mg) emodepside and 83.7 mg praziquantel.

(b) Sponsor. See No. 000859 in §510.600(c) of this chapter.

(c) Conditions of use in cats—(1) Amount. The recommended minimum dose is 1.36 mg/pound (lb) (3 mg/kilogram (kg)) emodepside and 5.45 mg/lb (12 mg/kg) praziquantel applied as a single topical dose.

(2) Indications for use. For the treatment and control of hookworm infections caused by *Ancylostoma tubaeforme* (adults and fourth-stage larvae), roundworm infections caused by *Toxocara cati* (adults and fourth-stage larvae), and tapeworm infections caused by *Dipylidium caninum* (adults) and *Taenia taeniaeformis* (adults).

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