Food and Drug Administration, HHS

§524.1139  Ivermectin topical solution.

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

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

(1) Nos. 050604, 055529, 058829, 061623 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

(2) Nos. 000859, 054925, and 086001 for use as in paragraphs (e)(1), (e)(2)(i), and (e)(3) of this section.

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

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

(e) Conditions of use in cattle—(1) Amount. One mL per 22 pounds (0.5 milligram per kilogram) of body weight applied topically to the back of the animal.

(2) Indications for use—(i) It is used for the treatment and control of Gastrointestinal roundworms (adults and fourth-stage larvae) Ostertagia ostertagi (including inhibited stage), Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. surnabada, Oesophagostomum radiatum; (adults) Strongyloides papillosus, Trichuris spp.; lungworms (adults and fourth-stage larvae) Dictyocaulus viviparous; cattle grubs (parasitic stages) Hypoderma

§524.1146  Imidacloprid and moxidectin.

(a) Specifications—(1) Each milliliter of solution contains 100 milligrams (mg) imidacloprid and 25 mg moxidectin for use as in paragraph (d)(1) of this section.

(2) Each milliliter of solution contains 100 mg imidacloprid and 10 mg moxidectin for use as in paragraphs (d)(2) and (d)(3) of this section.

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

(c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) Conditions of use in dogs—(1) Amount. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin, once a month.

(ii) Indications for use. For the prevention of heartworm disease caused by Dirofilaria immitis; for the treatment and control of ear mite (Otodectes cynotis) infestations, intestinal roundworms (Toxocara canis), and hookworms (Ancylostoma tubaeforme); kills adult fleas and treats flea infestations (Ctenocephalides felis).

(3) Ferrets—(i) Amount. Topically apply 9.0 mg/lb body weight (20 mg/kg) imidacloprid and 0.9 mg/lb (2 mg/kg) moxidectin, once a month.

(ii) Indications for use. For the prevention of heartworm disease caused by Dirofilaria immitis; kills adult fleas (Ctenocephalides felis) and is indicated for the treatment of flea infestations on ferrets.

[72 FR 10597, Mar. 9, 2007, as amended at 78 FR 73698, Dec. 9, 2013]
§ 524.1195 Ivermectin otic suspension.

(a) Specifications. Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer the contents of one 0.5-mL tube topically into each external ear canal.

(2) Indications for use. For the treatment of adult ear mite (Otodectes cynotis) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven.

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

§ 524.1200a Kanamycin ophthalmic ointment.

(a) Specifications. Each gram of ointment contains 3.5 milligrams kanamycin activity as kanamycin sulfate.

(b) Sponsor. See No. 054771 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Apply a thin film to the affected eye three or four times daily or more frequently if deemed advisable. Treatment should be continued for at least 48 hours after the eye appears normal.

(2) Indications for use. For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.

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

§ 524.1200b Kanamycin ophthalmic solution.

(a) Specifications. Each milliliter of solution contains 10 milligrams kanamycin activity as kanamycin sulfate.

(b) Sponsor. See No. 054771 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Administer as frequently as possible for the first 48 hours, after which the frequency of applications may be decreased. Treatment should be continued for at least 48 hours after the eye appears normal.

(2) Indications for use. For the treatment of various eye infections (conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations) due to bacteria sensitive to kanamycin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.