Food and Drug Administration, HHS

§ 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) Conditions of Use in Dogs—(1) Amount. The recommended minimum dosage is 4.5 mg/pound (lb) (10 mg/kilogram (kg)) of imidacloprid and 36.4 μg/lb (80 μg/kg) of ivermectin, topically once a month.

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

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

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§ 524.1193 Ivermectin topical solution.

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

(b) Sponsors. 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), (e)(2)(ii), 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 viviparus; cattle grubs (parasitic stages) Hypoderma milligrams (mg) imidacloprid and 800 micrograms (μg) ivermectin.

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

(c) Conditions of Use in Dogs—(1) Amount. The recommended minimum dosage is 4.5 mg/pound (lb) (10 mg/kilogram (kg)) of imidacloprid and 36.4 μg/lb (80 μg/kg) of ivermectin, topically once a month.

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

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

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bovis, H. lineatum; mites Sarcoptes scabiei var. bovis; lice Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenoptes capillatus; and horn flies Haematobia irritans.

(ii) It controls infections and prevents reinfection with O. ostertagi, O. radiatum, H. placei, T. axei, C. punctata, and C. oncophora for 14 days after treatment.

(iii) It controls infections and prevents reinfection with O. radiatum and D. viviparus for 28 days after treatment, C. punctata and T. axei for 21 days after treatment, O. ostertagi, H. placei, C. oncophora, and C. surnabada for 14 days after treatment, and D. bovis for 56 days after treatment.

(3) Limitations. Do not treat cattle within 48 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 on preruminating calves. Do not use on calves to be processed for veal.

§ 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.

§ 524.1195a Ivermectin ophthalmic dosage forms.

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

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

(c) Conditions of use—(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 ivermectin. 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.

§ 524.1195b Ivermectin ophthalmic solution.

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

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

(c) Conditions of use—(1) Amount. Instill a few drops into the affected eye every 3 hours 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 ivermectin. For prophylaxis in traumatic conditions, removal of foreign bodies, and intraocular surgery.