§ 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)(2)(iii) of this section.

(2) Nos. 054925, 059130, and 066916 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 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 §519.600(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.


§ 524.1200 Kanamycin ophthalmic and topical dosage forms.

§ 524.1200a Kanamycin ophthalmic ointment.

(a) Specifications. The drug, which is in a suitable and harmless ointment base, contains 3.5 milligrams of kanamycin activity (as the sulfate) per gram of ointment.

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

(c) Conditions of use. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. 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. For use only by or on the order of a licensed veterinarian.

§ 524.1200b Kanamycin ophthalmic aqueous solution.

(a) Specifications. The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10 milligrams of kanamycin activity (as the sulfate) per milliliter of solution.

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

(c) Conditions of use. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used in treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulceraions and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. 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. For use only by or on the order of a licensed veterinarian.

§ 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.

(a) Specifications. (1) Calcium amphomycin is the calcium salt of amphomycin. It conforms to the following specifications:

(i) Its potency is not less than 863 micrograms of amphomycin per milligram;

(ii) Its moisture content is not more than 10 percent; and

(iii) Its pH in a 2-percent aqueous suspension is 6.0 to 7.5.

(2) The drug is in a water-miscible ointment or cream base and each gram of ointment or cream contains: 5.0 milligrams of kanamycin activity as the sulfate, 5.0 milligrams of amphomycin activity as the calcium salt, and 10.0 milligrams of hydrocortisone acetate.

(b) Sponsor. See No. 000061 and 053501 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.350 of this chapter.

(d) Conditions of use. Cattle—(1) Amount. 2.5 milliliters per 110 pounds (10 milligrams of levamisole per kilogram) of body weight as a single dose topically to the back of the animal.

(2) Indications for use. Anthelmintic effective against stomach worms (Haemonchus, Trichostrongylus, Ostertagia), intestinal worms (Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia), and lungworms (Dictyocaulus).