

sulfate equivalent to 3 milligrams (mg) of gentamicin base and 1 mg betamethasone acetate equivalent to 0.89 mg betamethasone alcohol.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Instill one or two drops of solution in the conjunctival sac three or four times a day.

(2) *Indications for use*. For treatment of external bacterial infections of the eye (conjunctiva and cornea).

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

[75 FR 54492, Sept. 8, 2010]

**§ 524.1132 Hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate otic suspension.**

(a) *Specifications*. Each milliliter (mL) of suspension contains 1.11 milligrams (mg) of hydrocortisone aceponate, 15.1 mg of miconazole nitrate, and 1,505 micrograms of gentamicin sulfate.

(b) *Sponsor*. See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Instill 1.0 mL in the affected ear once daily for 5 days.

(2) *Indications for use*. For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

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

[76 FR 78150, Dec. 16, 2011]

**§ 524.1140 Imidacloprid and ivermectin.**

(a) *Specifications*. The product is available in unit applicator tubes containing 0.4, 1.0, 2.5, or 4.0 milliliters (mL). Each mL of solution contains 100 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.

[67 FR 78685, Dec. 26, 2002]

**§ 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 paragraph (d)(2) 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*—(1) *Dogs*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 1.1 mg/lb (2.5 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; and the treatment and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and whipworms (*Trichuris vulpis*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(2) *Cats*—(i) *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 cati*), and hookworms (*Ancylostoma tubaeforme*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

[72 FR 10597, Mar. 9, 2007]