

(2) *Indications for use.* For the treatment of acute and chronic canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

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

[58 FR 38973, July 21, 1993, as amended at 63 FR 31932, June 11, 1998; 68 FR 42970, July 21, 2003; 70 FR 8291, Feb. 18, 2005; 71 FR 13542, Mar. 16, 2006; 71 FR 16481, Apr. 3, 2006; 71 FR 38261, July 6, 2006; 71 FR 56867, Sept. 28, 2006; 78 FR 17597, Mar. 22, 2013]

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

(a) *Specifications.* Each gram contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3 milligram (mg) gentamicin base, mometasone furoate monohydrate equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP.

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

(c) *Conditions of use in dogs*—(1) *Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

(2) *Indications for use.* For the treatment of otitis externa caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 15370, Mar. 31, 2003; 70 FR 36338, June 23, 2005]

§ 524.1044i Gentamicin and betamethasone ophthalmic solution.

(a) *Specifications.* Each milliliter (mL) of solution contains gentamicin 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*).