

§ 524.1044h

pounds, instill 8 drops twice daily for dogs weighing 30 pounds or more. For 215 g bottle, instill 2 drops of ointment twice daily into the ear canal of dogs weighing less than 30 pounds, instill 4 drops twice daily for dogs weighing 30 pounds or more. Therapy should continue for 7 consecutive days.

(3) The external ear should be cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable solutions. Excessive hair should be clipped from the treatment area. If hypersensitivity occurs, treatment should be discontinued and alternate therapy instituted.

(4) Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(5) 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]

§ 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 § 510.6(c) of this chapter.

(c) *Conditions of use—Dogs—*(1) *Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 5- and 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 5- and 30-g bottle into

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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]

§ 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]

§ 524.1193 Ivermectin pour-on.

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

(b) *Sponsors.* See Nos. 050604, 051259, 051311, 058829, 059130, and 066916 in § 510.600(c) of this chapter for use as in paragraph (e) 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.* (1) *Amount.* One mL per 22 pounds of body weight.

(2) *Indications for use in cattle.* It is used topically for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage