

§ 524.1044f Gentamicin and betamethasone spray.

(a) *Specifications.* Each milliliter of spray contains gentamicin sulfate equivalent to 0.57 milligram (mg) gentamicin base and betamethasone valerate equivalent to 0.284 mg betamethasone.

(b) See Nos. 000061, 054925, 058829, and 065531 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer two spray actuations two to four times daily for 7 days.

(2) *Indications for use.* For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin.

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

[71 FR 13542, Mar. 16, 2006, as amended at 72 FR 5929, Feb. 8, 2007; 74 FR 22822, May 15, 2009]

§ 524.1044g Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.

(a) *Specifications.* Each gram (g) of ointment contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base, betamethasone valerate equivalent to 1 mg betamethasone, and 10 mg clotrimazole.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(1) No. 000061 for use of 7.5- or 15-gram (g) tubes, 12.5-, 30-, or 215-g bottles.

(2) No. 054925 for use of 7.5- or 15-g tubes; 10-, 15-, 25-, or 215-g bottles.

(3) No. 059130 for use of 10-, 20-, 40-, or 215-g bottles.

(3) No. 059130 for use of 10-, 20-, or 215-g bottles.

(4) No. 025463 for use of 7.5- or 15-g tubes, or 215-g bottles.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill ointment twice daily into the ear canal for 7 consecutive days.

(i) From 7.5- or 15-g tubes; 10-, 12.5-, 15-, 25-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

(ii) From 20-, 40-, or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(ii) From 20- or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(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]

§ 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]