

§ 524.1044c

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treatment. Excessive hair should be removed. A sufficient amount of the drug should be applied to cover the treatment area. The drug should be administered twice daily for 7 to 14 days.

(3) If hypersensitivity to any of the components occurs treatment with this product should be discontinued and appropriate therapy instituted. Concomitant use with other drugs known to induce ototoxicity is not recommended. This preparation should not be used in conditions where corticosteroids are contraindicated. Do not administer parenteral corticosteroids during treatment with this drug. The antibiotic sensitivity of the pathogenic organism should be determined prior to use of this preparation.

(4) For use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975. Redesignated at 41 FR 14189, Apr. 2, 1976, and amended at 52 FR 7832, Mar. 13, 1987; 61 FR 48624, Sept. 16, 1996]

§ 524.1044c **Gentamicin ophthalmic ointment.**

(a) *Specifications.* Each gram of sterile ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

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

(c) *Conditions of use.* (1) The drug is used on dogs and cats for topical treatment of conjunctivitis caused by susceptible bacteria.

(2) Apply approximately a ½-inch strip to the affected eye 2 to 4 times a day.

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

[41 FR 14188, Apr. 2, 1976, as amended at 52 FR 7832, Mar. 13, 1987]

§ 524.1044d **Gentamicin sulfate, betamethasone valerate ointment.**

(a) *Specifications.* Each gram of ointment contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone.

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

(c) *Conditions of use.* (1) The drug is used or indicated for use in dogs in the treatment of acute and chronic canine

otitis externa and canine infected superficial lesions caused by bacteria sensitive to gentamicin.

(2)(i) For the treatment of acute and chronic canine otitis externa the drug is administered by instillation of 3 to 8 drops into the ear canal twice daily for 7 days. The external ear and ear canal should be properly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area of the external ear.

(ii) For the treatment of canine infected superficial lesions, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. A sufficient amount of the drug should be applied to cover the treatment area. The drug should be administered twice daily for 7 to 14 days.

(3) If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. Concomitant use of drugs known to induce ototoxicity should be avoided. Observe patients for signs of adrenocorticoid overdosage. The antibiotic susceptibility of the pathogenic organism should be determined prior to use of this preparation. Administration of recommended doses beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.

(4) For use by or on the order of a licensed veterinarian.

[47 FR 26378, June 18, 1982, as amended at 52 FR 7832, Mar. 13, 1987]

§ 524.1044e **Gentamicin sulfate spray.**

(a) *Specification.* Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 1.07 milligrams of gentamicin.

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

(c) *Conditions of use.* (1) The drug is indicated for the treatment of pink eye in cattle (infectious bovine keratoconjunctivitis) caused by *Moraxella bovis*.

(2) One actuation of the sprayer delivers 0.7 milliliter containing 0.75 milligram gentamicin. The sprayer should be held upright 3 to 6 inches from the

affected eye, with the opening directed towards the eye, and pumped once. It is advisable to treat once a day for up to 3 days.

(3) Conditions other than bacterial infections of the bovine eye and infectious keratoconjunctivitis caused by *Moraxella bovis* may produce similar signs. If conditions persists or increases, discontinue use and consult veterinarian.

[48 FR 41157, Sept. 14, 1983, as amended 52 FR 7833, Mar. 13, 1987]

§ 524.1044f Gentamicin sulfate, betamethasone valerate topical spray.

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

(b) *Sponsor.* See Nos. 000061 and 051259 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs in the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin.

(2) For the treatment of infected superficial lesions, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. One actuation of the sprayer delivers 0.7 milliliter of the spray. The drug should be administered with two spray actuations 2 to 4 times daily for 7 days.

(3) If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. The antibiotic susceptibility of the pathogenic organism should be determined prior to use of this preparation. Administration of recommended doses beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.

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

[50 FR 740, Jan. 7, 1985, as amended at 52 FR 7833, Mar. 13, 1987; 62 FR 10220, Mar. 6, 1997]

§ 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. 051259 for use of 7.5- or 15-g tubes, 10-, or 25-g bottles.

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

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

(i) From 7.5- or 15-g tubes, 10-, 12.5-, 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 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 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]

§ 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