

§ 524.1044e

21 CFR Ch. I (4-1-11 Edition)

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 in-

creases, discontinue use and consult veterinarian.

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

§ 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, and 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.