§ 524.1044  Gentamicin ophthalmic and topical dosage forms.

(a) Specifications. Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base.

(b) Sponsors. See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

§ 524.1044a Gentamicin ophthalmic solution.

(a) Specifications. Each milliliter of sterile aqueous solution 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 in dogs and cats for the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

(2) Administer 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

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


§ 524.1044b Gentamicin and betamethasone otic solution.

(a) Specifications. Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) gentamicin base and betamethasone valerate equivalent to 1 mg betamethasone alcohol.

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

(c) Conditions of use—(1) Amounts and indications for use—(i) For the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin in dogs, instill three to eight drops of solution into the ear canal twice daily for 7 to 14 days.

(ii) For the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin in dogs and cats, apply a sufficient amount of the drug to cover the treatment area twice daily for 7 to 14 days.

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

[71 FR 13542, Mar. 16, 2006]

§ 524.1044c Gentamicin ophthalmic ointment.

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

(b) Sponsors. See Nos. 000061 and 043264 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs and cats—(1) Amount. Apply approximately a 1/2-inch strip to the affected eye 2 to 4 times a day.

(2) Indications for use. For treatment of conjunctivitis caused by susceptible bacteria.