

(iii) *Cattle*. For treatment of bacterial infections of the bovine eye and for treatment and to reduce the incidence of additional cases of infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

(iv) *Horses and ponies*. For treatment or prevention of bacterial infection of superficial wounds, abrasions, and lacerations caused by *Staphylococcus aureus*, *Streptococcus spp.* and *Proteus spp.* sensitive to furazolidone.

(3) *Limitations*. For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug once or twice daily, and repeat treatment as required. For treatment of bacterial infections of the bovine eye and infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*: Treat affected eyes once daily on each of 3 to 5 consecutive days; to reduce incidence of additional cases of infectious keratoconjunctivitis also medicate unaffected eyes. Evidence of clinical improvement of bovine eye infections should be noticeable after 5 treatments; if not, reconsult veterinarian. Use only as recommended by a veterinarian in treatment of puncture wounds, wounds requiring surgical debridement or suturing, those of a chronic nature involving proud flesh, generalized and chronic infections of the skin, and those skin conditions associated with intense itching. If redness, irritation, or swelling persists or increases, discontinue use and reconsult veterinarian. Not for use in horses intended for food.

[45 FR 49543, July 25, 1980, as amended at 50 FR 30153, July 24, 1985; 56 FR 50653, Oct. 8, 1991; 57 FR 31314, July 15, 1992; 60 FR 55659, Nov. 2, 1995]

**§ 524.1044 Gentamicin sulfate ophthalmic and topical dosage forms.**

**§ 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 con-

junctiva 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.

[41 FR 14189, Apr. 2, 1976, as amended at 52 FR 7832, Mar. 13, 1987]

**§ 524.1044b Gentamicin sulfate, betamethasone valerate otic solution.**

(a) *Specifications*. Each cubic centimeter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone alcohol.

(b) *Sponsor*. See Nos. 000061 and 051259 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 otitis externa caused by bacteria sensitive to gentamicin; the drug is also used or indicated for use in dogs and cats in the treatment of superficial infected lesions caused by bacteria sensitive to gentamicin.

(2)(i) For the treatment of acute and chronic canine otitis externa caused by bacteria sensitive to gentamicin, the drug is administered by instillation of 3 to 8 drops of solution into the ear canal twice daily for 7 to 14 days. Duration of treatment will depend upon the severity of the condition and the response obtained. The duration of treatment and/or frequency of the dosage may be reduced but care should be taken not to discontinue therapy prematurely. 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 and feline superficial infected lesions caused by bacteria sensitive to gentamicin, 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 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.