

equivalent to 3.5 milligrams of neomycin base, 5 milligrams of hydrocortisone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is indicated for treating acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats. In treatment of ear canker and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal may be applied one to three times daily.¹

(2) Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to the product. If such signs are noted, therapy with the product should be stopped. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly *Monilia*.¹

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 21922, May 24, 1984]

§ 524.1484e Neomycin sulfate and polymyxin B sulfate ophthalmic solution.

(a) *Specifications*. Each milliliter of the ophthalmic preparation contains 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 Units of polymyxin B sulfate.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is recommended for the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivitis, and blepharitis in the dog.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) The recommended dosage is 1 to 2 drops per eye every 6 hours.

(3) In treating ophthalmological conditions associated with bacterial infections the drug is contraindicated in those cases in which microorganisms are nonsusceptible to the antibiotics incorporated in the drug.

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

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996]

§ 524.1484f Neomycin sulfate, prednisolone acetate, tetracaine hydrochloride eardrops.

(a) *Specifications*. The product contains 5 milligrams of neomycin sulfate equivalent to 3.5 milligrams of neomycin base, 2.5 milligrams of prednisolone acetate, and 5 milligrams of tetracaine hydrochloride in each milliliter of sterile suspension.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is useful in treating such conditions as acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats. It is indicated as treatment or adjunctive therapy of certain ear conditions in dogs and cats caused by or associated with neomycin-susceptible organisms and/or allergy. In otitis externa, 2 to 6 drops may be placed in the external ear canal two or three times daily.¹

(2) Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly *Monilia*. Thus, if improvement is not noted within 2 or 3 days, or if redness, irritation, or swelling persists or increases, the diagnosis should be re-determined and appropriate therapeutic measures initiated. Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy. If such signs are noted, therapy should be stopped.¹

§ 524.1484g

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

§ 524.1484g Neomycin sulfate-thiabendazole-dexamethasone solution.

(a) *Specifications.* Each cubic centimeter of neomycin sulfate-thiabendazole-dexamethasone solution contains: 40 milligrams of thiabendazole, 3.2 milligrams of neomycin (from neomycin sulfate), and 1 milligram of dexamethasone.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for use as an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats.

(2) In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (two to four drops per square inch) twice daily. In treating otitis externa, five to 15 drops of the drug should be instilled in the ear twice daily. The drug is limited to 7 days maximum duration of administration.

(3) For use only by or on order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

§ 524.1484h Neomycin, penicillin, polymyxin, hydrocortisone suspension.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams of neomycin sulfate equivalent to 17.5 milligrams of neomycin, 10,000 international units of penicillin G procaine, 5,000 international units of polymyxin B sulfate, 2 milligrams of hydrocortisone acetate, and 1.25 milligrams of hydrocortisone sodium succinate.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) *Special considerations.* The labeling shall state: This medication contains penicillin. Allergic reactions in humans are known to occur from topical exposure to penicillin.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

21 CFR Ch. I (4-1-13 Edition)

(d) *Conditions of use—dogs—*(1) *Amount.* Rub a small amount into the involved area 1 to 3 times a day. After definite improvement, it may be applied once a day or every other day.

(2) *Indications for use.* Treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

(3) *Limitations.* For use in dogs only. Shake drug thoroughly and clean lesion before using. If redness, irritation, or swelling persists or increases, discontinue use and reevaluate diagnosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 5105, Feb. 3, 1994]

§ 524.1484i Neomycin sulfate, hydrocortisone acetate, sterile ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, and 5 milligrams of hydrocortisone acetate in each gram of ointment.¹

(b) *Sponsor.* No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* Apply three or four times daily into the conjunctival sac. With improvement, frequency may be reduced to two or three times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal one to three times daily.¹

(2) *Indications for use.* For treating infections, allergic, and traumatic keratitis, conjunctivitis, acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats.¹

(3) *Limitations.* All topical ophthalmic preparations containing corticosteroids, with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until infection is under control and corneal regeneration is well underway. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use on antibiotic-containing preparations resulting in overgrowth of nonsusceptible