§ 524.1484c Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of isoflupredone 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 used in treating such conditions as acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It is also effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

(2) In treatment of otitis externa 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. When used on the skin or mucous membranes, the affected area should be cleansed, and a small amount of the ointment applied and spread or rubbed in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response.

(3) 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 drug. If such signs are noted, therapy with the drug should be stopped. Treatment should be limited to the period when local anesthesia is essential to control self-inflicted trauma.

(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 43 FR 18172, Apr. 28, 1978]

§ 524.1484d Neomycin sulfate, hydrocortisone acetate, tetracaine hydrochloride ear ointment.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, 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, keratoconjunctivities, and blepharitis in the dog.

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[1] These 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.