

use in pregnant or breeding animals has not been determined. Not for ophthalmic use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[53 FR 39085, Oct. 5, 1988, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use in dogs and cats for the treatment of superficial ocular bacterial infections limited to the conjunctival or the anterior segment of the eye.

(2) The drug is applied four times each day.

(3) The drug is applied by inserting the tip of the tube beneath the lower lid and by expressing a small quantity of ointment into the conjunctival sac. The tip of the tube should not come in contact with the eye surface.

(4) Severe infections should be supplemented by systemic therapy.

(5) Prolonged administration of the drug may permit overgrowth of organisms that are not susceptible to neomycin. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken.

(6) 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 44 FR 49666, Aug. 24, 1979]

§ 524.1484b Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 1 milligram of isoflupredone acetate, 5 milligrams of tetracaine hydrochloride and .2 milligram of

myristyl-gamma-picolinium chloride in each gram of the product in a special adherent powder base.

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

(c) *Conditions of use.* (1) It is used in horses, dogs, and cats in the treatment or adjunctive therapy of certain ear and skin conditions when such conditions are caused by or associated with neomycin-susceptible organisms and/or allergy. In addition the product is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable. The product may be used as a dusting powder following amputation of tails, claws, and dew-claws and following ear trimming, castrating, and such surgical procedures as ovariohysterectomies. The product may also be used in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital dermatitis in dogs.

(2) 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]

§ 524.1484c 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 also is 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 pro-

longed 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.

(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.

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.