

§ 524.1484f

21 CFR Ch. I (4–1–01 Edition)

§ 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

(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.

(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

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.