

Food and Drug Administration, HHS

§ 524.1580b

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 organisms, particularly *Monilia*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[43 FR 40456, Sept. 12, 1978]

§ 524.1484j [Reserved]

§ 524.1484k Neomycin sulfate, prednisolone, tetracaine, and squalane topical-otic suspension.

(a) *Specifications.* Each milliliter of suspension contains 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base), 2 milligrams prednisolone, 5 milligrams tetracaine, and 0.25 milliliter squalane.

(b) *Sponsor.* See 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 2 to 3 applications daily or as needed.

(2) *Indications for use.* Indicated for use in dogs and cats for treating acute otitis externa and as adjunctive therapy in management of chronic otitis externa. The product may also be used for treating moist dermatitis in dogs.

(3) *Limitations.* Tetracaine and neomycin have the potential to sensitize. If signs of irritation or sensitivity develop, discontinue use. Prolonged use of this product may result in overgrowth of nonsusceptible organisms. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 5265, Feb. 4, 1983; 48 FR 8055, Feb. 25, 1983]

§ 524.1580 Nitrofurazone ophthalmic and topical dosage forms.

§ 524.1580a [Reserved]

§ 524.1580b Nitrofurazone ointment.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) See Nos. 000010, 000069, 050749, 054925, 058005, and 061623 for use on dogs, cats, or horses.

(2) See No. 017135 for use on dogs and horses.

(3) See Nos. 017153 and 058829 for use on horses.

(c) [Reserved]

(d) *Conditions of use—(1) Amount.* Apply directly on the lesion with a spatula or first place on a piece of gauze. The preparation should remain on the lesion for at least 24 hours. Use of a bandage is optional.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.

(3) *Limitations.* For use only on dogs, cats, and horses. Do not use in horses intended for human consumption. Federal law prohibits the use of this product in food-producing animals. In case of deep or puncture wounds or serious