

§ 524.1600

21 CFR Ch. I (4–1–13 Edition)

swelling persists or increases, discontinue use; consult veterinarian.¹

[49 FR 9417, Mar. 13, 1984, as amended at 71 FR 13542, Mar. 16, 2006]

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

§ 524.1600a Nystatin, neomycin, thioestrepton, and triamcinolone acetate ointment.

(a) *Specifications.* Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thioestrepton; and 1.0 milligram of triamcinolone acetate.

(b) *Sponsors.* For petrolatum base ointments see 000069, 000856, 025463, 053501, and 054925 in § 510.600(c) of this chapter. For vanishing cream base ointments see Nos. 025463, 053501, and 054925.

(c) *Conditions of use*—(1) *Amount.* (i) For topical dermatological use: Clean affected areas and remove any encrusted discharge or exudate, and apply sparingly either ointment in a thin film.

(ii) For otic use: Clean ear canal of impacted cerumen, remove any foreign bodies such as grass awns and ticks, and instill three to five drops of petrolatum base ointment. Preliminary use of a local anesthetic may be advisable.

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.

(2) *Indications for use.* (i) Topically: Use either ointment in dogs and cats for anti-inflammatory, antipruritic, antifungal, and antibacterial treatment of superficial bacterial infections, and for dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections.

(ii) Otitis, cysts, and anal gland infections: Use petrolatum base ointment in dogs and cats for the treatment of acute and chronic otitis and interdigital cysts, and in dogs for anal gland infections.

(3) *Limitations.* For mild inflammations, use once daily to once a week. For severe conditions, apply initially

two to three times daily, decreasing frequency as improvement occurs. Not intended for treatment of deep abscesses or deep-seated infections. Not for ophthalmic use. 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 29770, July 11, 1978; 50 FR 41490, Oct. 11, 1985; 53 FR 39257, Oct. 6, 1988; 54 FR 5431, Feb. 3, 1989; 54 FR 48090, Nov. 21, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 61 FR 63712, Dec. 2, 1996; 64 FR 42831, Aug. 6, 1999; 67 FR 67521, Nov. 6, 2002; 68 FR 55201, Sept. 23, 2003; 70 FR 50183, Aug. 26, 2005; 71 FR 13542, Mar. 16, 2006]

§ 524.1600b Nystatin, neomycin, thioestrepton, and triamcinolone acetate ophthalmic ointment.

(a) *Specifications.* Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units of thioestrepton, and 1.0 milligram of triamcinolone acetate.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for ophthalmic use as an anti-inflammatory, antipruritic, antifungal (*Candida albicans*), and antibacterial ointment for local therapy in keratitis and conjunctivitis in cats and dogs and for infectious keratoconjunctivitis (pink eye) in cattle.

(2) It is to be administered as follows:

(i) For conjunctivitis and keratitis: Apply one drop of ointment to the affected eye(s) two or three times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) For bovine infectious keratoconjunctivitis: Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(iii) Frequency of administration is dependent on the severity of the condition. For mild inflammations, applications may range from once daily to once a week; for severe conditions the drug may be applied as often as two to three times daily. Frequency of treatment may be decreased as improvement occurs.

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

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 524.1610 Orbifloxacin, mometasone furoate monohydrate, and posaconazole suspension.

(a) *Specifications.* Each gram of suspension contains 10 milligrams (mg) orbifloxacin, mometasone furoate monohydrate equivalent to 1 mg mometasone furoate, and 1 mg posaconazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* For dogs weighing less than 30 lbs. instill 4 drops once daily into the ear canal. For dogs weighing 30 lbs. or more, instill 8 drops into the ear canal. Therapy should continue for 7 consecutive days.

(2) *Indications for use.* For the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase-positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*).

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

[75 FR 16346, Apr. 1, 2010]

§ 524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.

§ 524.1662a Oxytetracycline hydrochloride and hydrocortisone spray.

(a) *Specifications.* Each 3-ounce unit of oxytetracycline hydrochloride and hydrocortisone spray contains 300 milligrams of oxytetracycline hydrochloride and 100 milligrams of hydrocortisone with an inert freon propellant such that a 1-second spray treatment will deliver approximately 2.5 milligrams of oxytetracycline hydrochloride and 0.8 milligram of hydrocortisone.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions. The indications include prevention of bacterial infections in super-

ficial wounds, cuts, and abrasions, treatment of allergic dermatoses, including urticaria, eczemas, insect bites, and cutaneous drug reactions, infections associated with minor burns and wounds, and nonspecific pruritus in dogs and cats.

(2) A small quantity should be sprayed on the affected surface by holding the container about 6 inches from the area to be treated and pressing the nozzle for 1 or 2 seconds. Only sufficient spray to coat the skin thinly is necessary. The application of small amounts at frequent intervals will give best results. Before treating animals with long or matted hair, it may be necessary to clip the affected area or spread the hairs to allow the medication to contact the skin surface. Relief may be noted following the first or second treatment; however, treatment should not be discontinued too soon after the initial favorable response has been obtained.

(3) Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

§ 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains oxytetracycline hydrochloride equivalent to 5 milligrams of oxytetracycline and 10,000 units of polymyxin B sulfate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae, *E. coli*, and *A. aerogenes* (such as conjunctivitis, keratitis, pink-eye, corneal ulcer, and blepharitis in dogs, cats, cattle, sheep, and horses); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other infectious diseases in dogs, cats, cattle, sheep, and horses.