

§ 524.1580c

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

[46 FR 43402, June 27, 1980, as amended at 49 FR 6476, Feb. 22, 1984; 50 FR 49373, Dec. 2, 1985; 52 FR 18691, May 19, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 29544, July 13, 1989; 54 FR 37097, Sept. 7, 1989; 55 FR 8462, Mar. 8, 1990; 55 FR 20455, May 17, 1990; 56 FR 37473, Aug. 7, 1991; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997; 66 FR 14074, Mar. 9, 2001]

§ 524.1580c Nitrofurazone soluble powder.

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

(b) *Sponsor.* See Nos. 000010, 000069, and 050749 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Apply several times daily to the lesion or affected area from the plastic squeeze bottle.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, skin ulcers, and abscesses after incision.¹

(3) *Limitations.* In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian. For use only on dogs, cats, and horses (not for food use).¹

[45 FR 43402, June 27, 1980, as amended at 47 FR 43368, Oct. 1, 1982; 48 FR 28984, June 24, 1983; 53 FR 40728, Oct. 18, 1988; 54 FR 30542, July 21, 1989; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997]

§ 524.1580d [Reserved]

§ 524.1580e Nitrofurazone ointment with butacaine sulfate.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone and 0.5 percent butacaine sulfate in a water-soluble base.

(b) *Sponsor.* See No. 051259 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For prevention or treatment of surface bacterial infections of ears, wounds, burns, and cutaneous ulcers of dogs, cats, and horses.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these

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(2) *Limitations.* Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The dressing may be changed several times daily or left on the lesion for a longer period. For use only on dogs, cats, and horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.¹

[49 FR 9417, Mar. 13, 1984]

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetone 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 thiostrepton; and 1.0 milligram of triamcinolone acetone.

(b) *Sponsors.* For petrolatum base ointments see 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter. For vanishing cream base ointments see 051259 and 053501.

(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,

uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.