

§ 524.1580

to 1 drop 2 to 4 times daily. For otitis externa, place 2 to 6 drops in the external ear canal 2 or 3 times daily.

(2) *Indications for use.* For the treatment of treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa.

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

[79 FR 10971, Feb. 27, 2014]

§ 524.1580 Nitrofurazone topical dosage forms.

§ 524.1580a 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. 050749, 054628, 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 burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

[46 FR 43402, June 27, 1980. Redesignated at 79 FR 10971, Feb. 27, 2014]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 524.1580a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

21 CFR Ch. I (4–1–14 Edition)

§ 524.1580b Nitrofurazone soluble powder.

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

(b) *Sponsor.* See No. 054628 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.

(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).

[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; 76 FR 17778, Mar. 31, 2011; 78 FR 21060, Apr. 9, 2013. Redesignated at 79 FR 10971, Feb. 27, 2014]

§ 524.1580c Nitrofurazone and butacaine ointment.

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

(b) *Sponsor.* See No. 054925 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.

(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