§ 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. 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.


§ 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).


§ 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 veterinarian. If redness, irritation, or
swelling persists or increases, discontinue use; consult veterinarian.

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone 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 acetonide.

(b) Sponsors. For petrolatum baseointments see Nos. 000856, 025463, 054771, and 054925 in §510.600(c) of this chapter. For vanishing cream base ointments see Nos. 025463, 054771, 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone 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 thiostrepton, and 1.0 milligram of triamcinolone acetonide.

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

(c) Conditions of use—(1) Dogs and cats—(i) Amount. Apply 1 drop of ointment to the affected eye(s) 2 or 3 times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) Indications for use. For use as an anti-inflammatory, antipruritic, antifungal (Candida albicans), and antibacterial ointment for local therapy in keratitis and conjunctivitis.

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

(2) Cattle—(i) Amount. Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) Indications for use. For infectious kerato-conjunctivitis (pinkeye).

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

§ 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.