

§ 524.1465

§ 524.1465 Mupirocin.

(a) *Specifications.* Each gram of ointment contains 20 milligrams mupirocin.

(b) *Sponsors.* See Nos. 000069 and 025463 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Apply twice daily. Treatment should not exceed 30 days.

(2) *Indications for use.* For the topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *S. intermedius*.

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

[72 FR 18119, Apr. 11, 2007]

§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use in dogs and cats for the treatment of superficial ocular bacterial infections limited to the conjunctival or the anterior segment of the eye.

(2) The drug is applied four times each day.

(3) The drug is applied by inserting the tip of the tube beneath the lower lid and by expressing a small quantity of ointment into the conjunctival sac. The tip of the tube should not come in contact with the eye surface.

(4) Severe infections should be supplemented by systemic therapy.

(5) Prolonged administration of the drug may permit overgrowth of organisms that are not susceptible to neomycin. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken.

(6) 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 44 FR 49666, Aug. 24, 1979]

21 CFR Ch. I (4–1–10 Edition)

§ 524.1484b Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 1 milligram of isoflupredone acetate, 5 milligrams of tetracaine hydrochloride and .2 milligram of myristyl-gamma-picolinium chloride in each gram of the product in a special adherent powder base.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses, dogs, and cats in the treatment or adjunctive therapy of certain ear and skin conditions when such conditions are caused by or associated with neomycin-susceptible organisms and/or allergy. In addition the product is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable. The product may be used as a dusting powder following amputation of tails, claws, and dew-claws and following ear trimming, castrating, and such surgical procedures as ovariectomies. The product may also be used in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital dermatitis in dogs.

(2) 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 18172, Apr. 28, 1978]

§ 524.1484c Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of isoflupredone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in treating such conditions as acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is