

§ 524.390

this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997]

§ 524.390 Chloramphenicol ophthalmic and topical dosage forms.

§ 524.390a Chloramphenicol ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams chloramphenicol in a petrolatum base.

(b) *Sponsor.* See Nos. 000856 and 025463 in § 510.600(c) of this chapter for use as in paragraph (c)(1)(i) of this section. See No. 017030 for use as in paragraph (c)(1)(ii) of this section.

(c) *Conditions of use. Dogs and cats.* (1) *Amount.* Apply as follows:

(i) Every 3 hours around the clock for 48 hours after which night instillations may be omitted.

(ii) Four to six times daily to affected eye for the first 72 hours depending upon the severity of the condition. A small amount of ointment should be placed in the lower conjunctival sac.

(2) *Indications for use.* Treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

(3) *Limitations.* Continue treatment for 48 hours (2 days) after eye appears normal. Therapy for cats should not exceed 7 days. Prolonged use in cats may produce blood dyscrasias. If improvement is not noted in a few days a change of therapy should be considered. When infection may be cause of disease, especially in purulent or catarrhal conjunctivitis, attempts should be made to determine through susceptibility testing, which antibiotics will be effective prior to applying ophthalmic preparations. This chloramphenicol product must not be used in animals producing meat, eggs, or milk. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]

21 CFR Ch. I (4-1-03 Edition)

§ 524.390b Chloramphenicol ophthalmic solution.

(a) *Specifications.* Each milliliter contains 5 milligrams of chloramphenicol.

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

(c) *Conditions of use. Dogs and Cats.* (1) *Amount.* Apply one or two drops, 4 to 6 times a day for the first 72 hours, depending upon the severity of the condition. Intervals between applications may be increased after the first 2 days.

(2) *Indications for use.* Treatment of bacterial conjunctivitis caused by organisms susceptible to chloramphenicol. Therapy should be continued for 48 hours after the eye appears normal.

(3) *Limitations.* Therapy for cats should not exceed 7 days. As with other antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs, or if clinical improvement is not noted within a reasonable period, discontinue use, and institute appropriate therapy. Prolonged use in cats may produce blood dyscrasias. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992]

§ 524.390d Chloramphenicol-prednisolone ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams of chloramphenicol and 2.5 milligrams of prednisolone acetate.

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

(c) *Conditions of use. Dogs and cats.* (1) *Amount.* Apply 4 to 6 times daily to the affected eye for the first 72 hours depending upon the severity of the condition. Continue treatment for 48 hours after the eye appears normal.

(2) *Indications for use.* Treatment of bacterial conjunctivitis and ocular inflammation caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Therapy for cats should not exceed 7 days, prolonged use in cats may produce blood dyscrasia. As with other antibiotics, prolonged

use may result in overgrowth of non-susceptible organisms. If superinfection occurs or if clinical improvement is not noted within a reasonable period, discontinue use and institute appropriate therapy. All topical ophthalmic preparations containing corticosteroids, with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37334, Aug. 18, 1992]

§ 524.402 Chlorhexidine ointment.

(a) *Specifications.* The product contains 1-percent chlorhexidine acetate in an ointment base.

(b) *Sponsor.* See Nos. 000856 and 058829 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* Use as a topical antiseptic ointment for surface wounds on dogs, cats, and horses.

(2) *Limitations.* Not for use in horses intended for food.

[67 FR 8860, Feb. 27, 2002]

§ 524.450 Clotrimazole cream.

(a) *Specifications.* Each gram of cream contains 10 milligrams of clotrimazole.

(b) *Sponsor.* See 000859 in § 510.600(c).

(c) *Conditions of use*—(1) *Amount.* Apply ¼-inch ribbon of cream per square inch of lesion once daily for 2 to 4 weeks.

(2) *Indications of use.* For the treatment of fungal infections of dogs and cats caused by *Microsporum canis* and *Trichophyton mentagrophytes*.

(3) *Limitations.* Wash hands thoroughly after use to avoid spread of infection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 48128, July 18, 1980]

§ 524.463 Copper naphthenate solution.

(a) *Specifications.* The drug contains 37.5 percent copper naphthenate in a suitable solvent.

(b) *Sponsor.* See Nos. 000856 and 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*—*Horses and ponies*—(1) *Amount.* Apply daily to affected hooves until fully healed.

(2) *Indications for use.* As an aid in treating horses and ponies for thrush caused by organisms susceptible to copper naphthenate.

(3) *Limitations.* Use on horses and ponies only. Remove debris and necrotic material before applying. Avoid contact around eyes. Do not use on animals that are raised for food production. Do not contaminate feed. Do not allow runoff of excess drug into hair because contact with the drug may cause some hair loss.

[47 FR 4250, Jan. 29, 1982]

§ 524.520 Cuprimyxin cream.

(a) *Specifications.* The drug contains 0.5 percent cuprimyxin (6-methoxy-1-phenazinol 5, 10-dioxide, cupric complex) in an aqueous cream base.

(b) *Sponsor.* See No. 063238 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Cuprimyxin is a broad spectrum antibacterial and antifungal cream for the topical treatment of superficial infections in horses, dogs, and cats caused by bacteria, dermatophytes (*Trichophyton* spp., *Microsporum* spp.) and yeast (*Candida albicans*) affecting skin, hair, and external mucosae.

(2) The cream is applied twice daily to affected areas by rubbing into lesions. Treatment should be continued for a few days after clinical recovery to avoid possible relapses.

(3) After application to cutaneous areas, a change in color from dark green to pink is due to the liberation of free myxin from its copper complex.

(4) If no response is seen within seven days, diagnosis and therapy should be reevaluated. If any adverse local reaction is observed after topical application, discontinue treatment.