

Food and Drug Administration, HHS

§ 524.155

- 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.
- 524.1742 N-(Mercaptomethyl) phthalimide S-(O,O-dimethyl phosphorodithioate) emulsifiable liquid.
- 524.1880 Prednisolone-neomycin sulfate ophthalmic ointment.
- 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.
- 524.1881a [Reserved]
- 524.1881b Prednisolone acetate-neomycin sulfate sterile suspension.
- 524.1883 Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment.
- 524.1982 Proparacaine hydrochloride ophthalmic solution.
- 524.2098 Selamectin.
- 524.2101 Selenium disulfide suspension.
- 524.2350 Tolnaftate cream.
- 524.2481 Triamcinolone acetonide cream.
- 524.2482 Triamcinolone spray.
- 524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13873, Mar. 27, 1975, unless otherwise noted.

§ 524.86 Amitraz liquid.

(a) *Specifications.* Amitraz liquid contains 19.9 percent amitraz in an organic solvent.

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

(c) *Conditions of use*—(1) *Indications for use.* For dogs for the treatment of generalized demodicosis (*Demodex canis*).

(2) *Amount.* One 10.6 milliliter bottle per 2 gallons of warm water (250 parts per million) for each treatment, for a total of 3 to 6 treatments, 14 days apart.

(3) *Limitations.* Continue treatment until no viable mites are found in skin scrapings at 2 successive treatments, or until 6 treatments have been applied. Do not use for treatment of localized demodicosis or scabies. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 18589, Apr. 30, 1982]

§ 524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

(a) *Sponsor.* To firms identified in § 510.600(c) of this chapter as follows:

(1) To 000009; each gram contains 500 units of bacitracin, 3.5 milligrams of

neomycin, and 10,000 units of polymyxin B.

(2) To 000061 and 025463; each gram contains 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate.

(b) *Conditions of use. Dogs and Cats.* (1) *Amount.* Apply a thin film over the cornea 3 or 4 times daily.

(2) *Indications for use.* Treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to susceptible organisms.

(3) *Limitations.* Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts 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 61625, Nov. 19, 1997]

§ 524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.

(a) *Sponsor.* To firms identified in § 510.600(c) of this chapter as follows:

(1) To 000061; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone.

(2) To 025463; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone acetate.

(b) *Conditions of use. Dogs and cats.* (1) *Amount.* Apply a thin film over the cornea three or four times daily.

(2) *Indications for use.* For treating acute or chronic conjunctivitis caused by susceptible organisms.

(3) *Limitations.* 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. Federal law restricts

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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