

**Food and Drug Administration, HHS**

**§ 524.660a**

(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) *Sponsors.* See Nos. 000856, 017135, and 058829 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, as amended at 68 FR 55825, Sept. 29, 2003]

**§ 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.

(5) 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 45 FR 56799, Aug. 26, 1980; 66 FR 46706, Sept. 7, 2001]

**§ 524.575 Cyclosporine ophthalmic ointment.**

(a) *Specifications.* Each gram of ointment contains 2 milligrams of cyclosporine.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Apply a 1/4-inch strip of ointment to the affected eye(s) every 12 hours.

(2) *Indications for use.* For management of chronic keratoconjunctivitis sicca (KCS) and chronic superficial keratitis (CSK) in dogs.

(3) *Limitations.* Place ointment directly on cornea or into the conjunctival sac. Safety of use in puppies, pregnant or breeding animals has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 48651, Sept. 20, 1995, as amended at 62 FR 48940, Sept. 18, 1997]

**§ 524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.**

**§ 524.660a Dimethyl sulfoxide solution.**

(a) *Specifications.* Dimethyl sulfoxide contains 90 percent of dimethyl sulfoxide and 10 percent of water.

**§ 524.660b**

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used or intended for use as a topical application to reduce acute swelling due to trauma:

(i) In horses administered 2 or 3 times daily in an amount not to exceed 100 milliliters per day. Total duration of therapy should not exceed 30 days.

(ii) In dogs administered 3 or 4 times daily in an amount not to exceed 20 milliliters per day. Total duration of therapy should not exceed 14 days.

(2) Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food. Other topical medications should only be used when the dimethyl sulfoxide treated area is thoroughly dry. Do not administer by any other route.

(3) For use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 61 FR 5507, Feb. 13, 1996]

**§ 524.660b Dimethyl sulfoxide gel.**

(a) *Specifications.* Dimethyl sulfoxide gel, veterinary contains 90 percent dimethyl sulfoxide in an aqueous gel.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For use on horses and dogs as a topical application to reduce acute swelling due to trauma.

(2) *Amount—(i) Horses.* Administer 2 or 3 times daily in an amount not to exceed 100 grams per day. Total duration of therapy should not exceed 30 days.

(ii) *Dogs.* Administer 3 or 4 times daily in an amount not to exceed 20 grams per day. Total duration of therapy should not exceed 14 days.

(3) *Limitations.* Do not use in horses and dogs intended for breeding purposes or in horses slaughtered for food. Restricted to topical use on horses and dogs only. Due to rapid penetrating ability of dimethyl sulfoxide, rubber gloves should be worn when applying the drug. No other medications should be present on the skin prior to application of the drug. Federal law restricts

**21 CFR Ch. I (4–1–04 Edition)**

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

[40 FR 13873, Mar. 27, 1975, as amended at 48 FR 56205, Dec. 20, 1983; 61 FR 5507, Feb. 13, 1996]

**§ 524.770 Doramectin.**

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

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use—Cattle—(1) Amount.* 5 milligrams per 10 kilograms (5 milligrams per 22 pounds).

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, *Ostertagia ostertagi*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days, and *Haemonchus placei* for 35 days after treatment.

(3) *Limitations.* Administer as a single dose. Do not slaughter cattle within 45 days of latest treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[62 FR 65753, Dec. 16, 1997, as amended at 63 FR 68183, Dec. 10, 1998; 64 FR 49082, Sept. 10, 1999]

**§ 524.802 Enrofloxacin, silver sulfadiazine emulsion.**

(a) *Specifications.* Each milliliter contains 5 milligrams (mg) enrofloxacin and 10 mg silver sulfadiazine.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—Dogs—(1) Amount.* 5 to 10 drops for dogs weighing 35 pounds (lb) or less and 10 to 15 drops for dogs weighing more than 35 lb; applied twice daily for up to 14 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs.

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