

§ 520.1120

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

negative by appropriate culture. Not for use in horses intended for food.

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

(3) Dogs and cats: (i) *Amount*. 125- and 500-milligram tablets administered orally as follows:

(a) Daily (single or divided) dose:

Body weight (pounds)	Dosage (milligrams)
Up to 6	62.5
6 to 18	125
18 to 36	250
36 to 48	375
48 to 75	500

(b) Weekly (single) dose: If experience indicates that treatment is more effective for the drug given in large doses, administer at intervals of 7 to 10 days, a dose equal to 10 milligrams/pound of body weight × body weight × number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.

(ii) *Indications for use*. For treatment of fungal infections of the skin, hair, and claws caused by *Trichophyton mentagrophytes*, *T. rubrum*, *T. schoenleini*, *T. sulphurem*, *T. verrucosum*, *T. interdigitale*, *Epidermophyton floccosum*, *Microsporum gypseum*, *M. canis*, *M. audouini*.

(iii) *Limitations*. For satisfactory diagnosis, a microscopic tissue examination or culture is recommended prior to treatment. Treatment should be continued for 3 to 4 weeks in skin and hair infections, and up to 4 months for infections involving nails or claws. Clipping of hair, nails, and claws to help remove any remaining viable fungi is indicated. Safety for use of griseofulvin for pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 42948, Sept. 29, 1976; 43 FR 28458, June 30, 1978; 52 FR 7832, Mar. 13, 1987; 54 FR 30205, July 19, 1989]

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) *Chemical name*. 3-Choloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications*. Haloxon assay of not less than 96 percent by infrared spectrum at 8.62 microns.

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

(d) *Special considerations*. Do not use any drug, insecticide, pesticide, or other chemical having cholinesterase-inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(e) *Related tolerances*. See § 556.310 of this chapter.

(f) *Conditions of use*. It is used as a drench as follows:

(1) *Cattle* —(i) *Amount*. 141.5 grams per packet.

(ii) *Indications for use*. Control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(iii) *Limitations*. (a) Dissolve each packet in 32 fluid ounces of water and administer as follows:

Weight of animal (pounds)	Dose (fluid ounces)
Up to 100	1/2
100 to 150	3/4
150 to 200	1
200 to 300	1 1/2
300 to 450	2
450 to 700	3
700 to 1,000	4
1,000 to 1,200	5
Over 1,200	6

(b) Do not treat within 1 week of slaughter; do not treat dairy animals of breeding age; animals should be re-treated in 3 to 4 weeks.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 10333, Feb. 15, 1980; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.1120b Haloxon boluses.

(a) *Chemical name*. 3-Chloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications*. Each bolus contains 10.1 grams of haloxon.

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

(d) *Related tolerances*. See § 556.310 of this chapter.

(e) *Conditions of use*. (1) Haloxon bolus is an anthelmintic used in cattle for the control of gastrointestinal roundworms of the genera *Haemonchus*,

Ostertagia, *Trichostrongylus* and *Cooperia*.

(2) It is administered by giving one bolus per approximately 500 pounds body weight (35 to 50 milligrams per kilogram of body weight).

(3) For most effective results, re-treat animals in 3 to 4 weeks. If reinfection is likely to occur, additional re-treatments may be necessary.

(4) Do not use any drug, pesticide or other chemical having cholinesterase inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(5) Do not treat animals within one week of slaughter.

(6) Do not treat dairy animals of breeding age or older.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 61591, Oct. 29, 1979; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.1130 Hetacillin oral dosage forms.

§ 520.1130a Hetacillin potassium capsules.

(a) *Specifications*. Each capsule contains hetacillin potassium equivalent to 50, 100, or 200 milligrams of ampicillin.

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

(c) *Conditions of use*. (1) *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight, twice daily. In severe infections, up to three times daily, or up to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, up to 20 milligrams per pound of body weight twice daily.

(ii) *Indications for use*. Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations*. For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals raised for food production. Federal law

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

(2) *Cats*—(i) *Amount*. Administer 50 milligrams twice daily.

(ii) *Indications for use*. Treatment against strains of organisms sensitive to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(3) *Limitations*. For use in dogs and cats only. Continue treatment for 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer in a fasting state to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Not for use in animals raised for food production. Federal law restricts this drug to use only by or on the order of a licensed veterinarian.

[57 FR 37325, Aug. 18, 1992]

§ 520.1130b Hetacillin potassium oral suspension.

(a) *Specifications*. Each milliliter contains hetacillin potassium equivalent to 50 milligrams of ampicillin.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight twice daily. In severe infections, up to three times daily, or up to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, up to 20 milligrams per pound of body weight twice daily.

(ii) *Indications for use*. Treatment against strains of organisms susceptible to hetacillin potassium and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft-tissue infections, and postsurgical infections.

(iii) *Limitations*. For use in dogs only. Not for use in animals raised for food production. Continue treatment 48 to 72 hours after the animal has become afebrile or asymptomatic. Administer 1 to 2 hours prior to feeding to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.