

**§ 520.1130b**

**21 CFR Ch. I (4–1–01 Edition)**

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.

(2) *Cats—(i) Amount.* 50 milligrams 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 cats 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.

[57 FR 37326, Aug. 18, 1992]

**§ 520.1130c Hetacillin potassium tablets.**

(a) *Specifications.* Each tablet 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.* Oral 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 which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 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.

(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 which are raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37326, Aug. 18, 1992]

#### § 520.1157 Iodinated casein tablets.

(a) *Specifications.* Each 1-gram tablet contains 25 milligrams of iodinated casein.

(b) *Sponsor.* See No. 017762 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.*  $\frac{1}{5}$  to 1 tablet per 10 pounds of body weight (equivalent to 0.5 to 2.5 milligrams of iodinated casein per pound of body weight).

(2) *Indications for use.* For dogs for apparent decreased thyroid activity where the signs are alopecia, scaliness of the skin surface, loss of hair, sebor-

rhea, thickening of the skin, hyperpigmentation, and lethargy.

(3) *Limitations.* If no response is observed in 30 to 45 days, the drug should be withdrawn and the diagnosis reconsidered. Do not use in the presence of cardiac disease, ischemia, adrenal insufficiency, or nephrosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 22469, May 30, 1984]

#### § 520.1158 Iodochlorhydroxyquin boluses.

(a) *Specifications.* Each bolus contains 10 grams of iodochlorhydroxyquin.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 1 bolus (10 grams) daily for a 1,000-pound horse.

(2) *Indications for use.* For treatment of equine diarrhea.

(3) *Limitations.* For horses only; not to be administered to food-producing animals. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 8054, Feb. 25, 1983, as amended at 50 FR 41489, Oct. 11, 1985]

#### § 520.1182 Iron dextran oral suspension.

(a) *Specifications.* Each 1.8 milliliter contains 100 milligrams of elemental iron as ferric hydroxide in complex with a low molecular weight dextran and 0.2 percent phenol as a preservative.

(b) *Sponsor.* See 017800 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 100 milligrams of elemental iron to each pig.

(2) *Indications for use.* Prevention of iron deficiency anemia in baby pigs.

(3) *Limitations.* Treat each pig within 24 hours of farrowing. Administer 1.8 milliliters orally by automatic dose dispenser.

[45 FR 75199, Nov. 14, 1980]

#### § 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram of paste contains 0.0187 milligram (1.87 percent) or 0.00153 milligram (0.153 percent) of ivermectin.