

§ 520.1130b

21 CFR Ch. I (4–1–02 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