

**§ 520.90**

**21 CFR Ch. I (4–1–04 Edition)**

**§ 520.90 Ampicillin oral dosage forms.**

**§ 520.90a Ampicillin capsules.**

(a) *Specifications.* Each capsule contains 125 milligrams or 250 milligrams of ampicillin.

(b) *Sponsor.* See No. 000008 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 to 10 milligrams per pound of body weight, e.g., one 125 mg capsule per 14 to 25 pounds, given 2 to 4 times daily; for animals weighing 6 to 14 pounds, one capsule twice daily.

(ii) *Indications for use.* Treatment of urinary tract infections (cystitis) due to *Proteus* spp., hemolytic and non-hemolytic streptococci, beta hemolytic streptococci, and *Escherichia coli*. In upper respiratory tract infections tracheobronchitis (kennel cough), tonsillitis due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms. 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.* 125 milligrams twice daily; in more acute conditions three times daily.

(ii) *Indications for use.* Treatment of respiratory tract infections (bacterial pneumonia) due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, *E. coli*, and *Proteus* spp. In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contra-

indicated in infections caused by penicillinase-producing organisms. 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 37321, Aug. 18, 1992]

**§ 520.90b Ampicillin trihydrate tablets.**

(a) *Specifications.* Each tablet contains ampicillin trihydrate equivalent to 50 or 100 milligrams of ampicillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* *Dogs*—(1) *Amount.* 5 milligrams per pound of body weight, at 8-hour intervals, 1 to 2 hours prior to feeding, to be continued 36 to 48 hours after all symptoms have subsided. If no improvement is seen within 5 days, stop treatment, reevaluate diagnosis, and change therapy.

(2) *Indications for use.* Oral treatment of infections caused by susceptible organisms as follows: Upper respiratory infections, tonsillitis, and bronchitis due to *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and *Pasteurella* spp., urinary tract infections (cystitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli*, *P. mirabilis*, and *Enterococcus* spp.; gastrointestinal infections due to *Staphylococcus* spp., *Streptococcus* spp., *Enterococcus* spp., and *E. coli*; infections associated with abscesses, lacerations, and wounds caused by *Staphylococcus* spp., and *Streptococcus* spp.

(3) *Limitations.* Not for use in animals which have shown hypersensitivity to penicillin or for infections caused by penicillinase-producing organisms. 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 37321, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

**§ 520.90c Ampicillin trihydrate capsules.**

(a) *Specifications.* Each capsule contains ampicillin trihydrate equivalent to 125, 250, or 500 milligrams of ampicillin.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 to 10 milligrams per pound of body weight two or three times daily. In severe or acute conditions, 10 milligrams per pound of body weight, three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use.* Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (tracheobronchitis and tonsillitis); urinary tract infections (cystitis); bacterial gastroenteritis; generalized infections (septicemia) associated with abscesses, lacerations, and wounds; and bacterial dermatitis.

(iii) *Limitations.* The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 10 to 30 milligrams per pound of body weight or three times daily. Administer 1 to 2 hours prior to feeding.

(ii) *Indications for use.* Treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (bacterial pneumonia); urinary tract infections (cystitis); and generalized infections (septicemia) associated with abscesses, lacerations, and wounds.

(iii) *Limitations.* The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in animals known to be allergic to any of the penicillins. Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37321, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

#### § 520.90d Ampicillin trihydrate for oral suspension.

(a) *Specifications.* When reconstituted as directed, each milliliter contains ampicillin trihydrate equivalent to 25 milligrams of ampicillin.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 to 10 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding. In severe or acute conditions, 10 milligrams per pound of body weight 3 times daily.

(ii) *Indications for use.* Treatment of respiratory tract infections (tracheobronchitis and tonsillitis) due to *Escherichia coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., and *Proteus* spp.; bacterial gastroenteritis due to *E. coli*; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus* spp. and *Streptococcus* spp.; bacterial dermatitis due to *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Pseudomonas* spp.

(iii) *Limitations.* Duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate 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.

(2) *Cats*—(i) *Amount.* 10 to 30 milligrams per pound of body weight orally, 2 or 3 times daily, 1 to 2 hours prior to feeding.

(ii) *Indications for use.* Treatment of respiratory tract infections (bacterial pneumonia) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Proteus* spp.; urinary tract infections (cystitis) due to *E. coli*, *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Corynebacterium* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due