

§ 520.90d

21 CFR Ch. I (4-1-01 Edition)

(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

to *Staphylococcus* spp., *Streptococcus* spp., *Bacillus* spp., and *Pasteurella* 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.

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

§ 520.90e Ampicillin trihydrate soluble powder.

(a) *Specifications*. Each gram contains ampicillin trihydrate equivalent to 88.2 milligrams of ampicillin.

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

(c) *Related tolerances*. See § 556.40 of this chapter.

(d) *Conditions of use*. *Swine*—(1) *Amount*. 5 milligrams of ampicillin per pound of body weight twice daily, orally by gavage or in drinking water for up to 5 days.

(2) *Indications for use*. Oral treatment of porcine colibacillosis (*Escherichia coli*) and salmonellosis (*Salmonella* spp.) infections in swine up to 75 pounds of body weight, and bacterial pneumonia caused by *Pasteurella multocida*, *Staphylococcus* spp., *Streptococcus* spp., and *Salmonella* spp.

(3) *Limitations*. For use in swine only. Not for use in other animals which are raised for food production. Treated swine must not be slaughtered for food during treatment and for 24 hours following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993]

§ 520.90f Ampicillin trihydrate boluses.

(a) *Specifications*. Each bolus contains ampicillin trihydrate equivalent to 400 milligrams of ampicillin.

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

paragraph (d)(1), 000069 for use as in paragraph (d)(2).

(c) *Related tolerances*. See § 556.40 of this chapter.

(d) *Conditions of use*. *Nonruminating calves*—(1) *Amount*. 5 milligrams per pound of body weight twice daily for up to 5 days.

(i) *Indications for use*. Oral treatment of colibacillosis caused by *Escherichia coli*, bacterial enteritis caused by *Salmonella* spp., and bacterial pneumonia caused by *Pasteurella* spp.

(ii) *Limitations*. Treated calves must not be slaughtered for food during treatment and for 15 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Amount*. 5 milligrams per pound of body weight twice daily not to exceed 4 days.

(i) *Indications for use*. Oral treatment of bacterial enteritis (colibacillosis) caused by *E. coli*.

(ii) *Limitations*. Treated calves must not be slaughtered for food during treatment and for 7 days after the last treatment. Not for use in other animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37322, Aug. 18, 1992, as amended at 58 FR 61016, Nov. 19, 1993; 60 FR 55659, Nov. 2, 1995]

§ 520.100 Amprolium oral dosage forms.

§ 520.100a Amprolium drinking water.

(a) *Chemical name*. 1-(4-Amino-2-n-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Conditions of use*. It is used in drinking water as follows:

(1) *Chickens and turkeys*—(i) *Amount*. 20 percent soluble powder.

(ii) *Indications for use*. Treatment of coccidiosis.

(iii) *Limitations*. Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for from 3 to 5 days (in severe outbreaks, give amprolium at the 0.024