§ 522.90

(i) Indications for use—(A) Dogs. For treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus*, *Streptococcus spp.*, *Escherichia coli*, and *Proteus mirabilis*; genital urinary infections (cystitis) due to *S. aureus*, *Streptococcus spp.*, *E. coli*, and *P. mirabilis*; gastrointestinal infections (bacterial gastroenteritis) due to *S. aureus*, *Streptococcus spp.*, *E. coli*, and *P. mirabilis*; soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus*, *Streptococcus spp.*, *E. coli*, and *P. mirabilis*.

(B) Cats. For treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *S. aureus*, *Staphylococcus spp.*, *Haemophilus spp.*, *E. coli*, *Pasteurella spp.*, and *P. mirabilis*; genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus spp.*, *E. coli*, *P. mirabilis*, and *Corynebacterium spp.*; gastrointestinal infections due to *E. coli*, *Proteus spp.*, *Staphylococcus spp.*, and *Streptococcus spp.*; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus*, *Staphylococcus spp.*, *Streptococcus spp.*, *E. coli*, and *Pasteurella multocida*.

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

(2) Amount. Administer 3 to 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

(ii) Indications for use. For treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to *P. multocida*, *P. hemolytica*, *Haemophilus spp.*, *Staphylococcus spp.*, and *Streptococcus spp.* and acute necrotic pododermatitis (foot rot) due to *Fusobacterium necrophorum*.

(iii) Limitations. Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. Milk from treated cows must not be used for human consumption during treatment or for 48 hours (8 milkings) after last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(79 FR 16183, Mar. 25, 2014)

§ 522.90 Ampicillin injectable dosage forms.

(79 FR 16183, Mar. 25, 2014)

§ 522.90a Ampicillin trihydrate suspension.

(a) Specifications. (1) Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams (mg) of ampicillin.

(2) Each milliliter contains ampicillin trihydrate equivalent to 150 mg of ampicillin.

(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraphs (d)(1), (d)(2), (d)(3)(i)(A), (d)(3)(ii)(A), and (d)(4) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in paragraphs (d)(3)(ii)(B), (d)(3)(i)(B), and (d)(3)(iii) of this section.

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

(d) Conditions of use—(1) Cattle—(i) Amount. For enteritis: 3 mg per pound of body weight, intramuscularly, once or twice daily, for up to 3 days. For pneumonia: 3 mg per pound of body weight, intramuscularly, twice daily, for up to 3 days.

(ii) Indications for use. For treatment of bacterial enteritis in calves caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella spp.* susceptible to ampicillin.

(2) Swine—(i) Amount. 3 mg per pound of body weight by intramuscular injection, once or twice daily, for up to 3 days.

(ii) Indications for use. Treatment of bacterial enteritis (colibacillosis) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella spp.* susceptible to ampicillin.

21 CFR Ch. I (4–1–14 Edition)
(iii) **Limitations.** Treated animals must not be slaughtered for food use during treatment or for 15 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) **Dogs—(i) Amount—(A) 3 to 6 mg per pound of body weight by intramuscular injection, once or twice daily. Usual treatment is 3 to 5 days.**

(B) **3 to 5 mg of ampicillin per pound of body weight, once a day for up to 4 days.**

(ii) **Indications for use—(A) Treatment of respiratory tract infections due to *E. coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; tonsillitis due to *E. coli*, *Pseudomonas* spp., *Streptococcus* spp., and *Staphylococcus* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(B) Treatment of bacterial infections of the upper respiratory tract (tonsillitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli*, *Proteus* spp., and *Pasteurella* spp., and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*, when caused by susceptible organisms.

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

(4) **Cats—(i) Amount.** 5 to 10 mg per pound of body weight by intramuscular or subcutaneous injection, once or twice daily. Usual treatment is 3 to 5 days.

(ii) **Indications for use.** Treatment of generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.

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

[70 FR 16183, Mar. 25, 2014]

§ 522.90b **Ampicillin trihydrate powder for injection.**

(a) **Specifications.** Each milliliter of aqueous suspension constituted from ampicillin trihydrate powder contains 50, 100, or 250 milligrams (mg) ampicillin equivalents.

(b) **Sponsors.** See Nos. 000010 and 010515 in §510.600(c) of this chapter.

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

(d) **Conditions of use—(1) Dogs and cats—(i) Amount.** 3 mg/pound (lb) of body weight twice daily by subcutaneous or intramuscular injection.

(ii) **Indications for use.** For treatment of strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and post-surgical infections.

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

(2) **Cattle—(i) Amount.** 2 to 5 mg/lb of body weight once daily by intramuscular injection.

(ii) **Indications for use.** For treatment of respiratory tract infections caused by organisms susceptible to ampicillin, bacterial pneumonia (shipping fever, calf pneumonia, and bovine pneumonia) caused by *Aerobacter* spp., *Klebsiella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida*, and *Escherichia coli*.

(iii) **Limitations.** Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment and for 144 hours (6 days) after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.


§ 522.90c **Ampicillin sodium.**

(a) **Specifications.** Each milliliter of aqueous solution constituted from ampicillin sodium powder contains 300 milligrams (mg) ampicillin equivalents.

(b) **Sponsors.** See Nos. 010515 and 054771 in §510.600(c) of this chapter.

(c) **Conditions of use in horses—(1) Amount.** 3 mg per pound of body weight twice daily by intravenous or intramuscular injection.

(2) **Indications for use.** For the treatment of respiratory tract infections