

§ 522.90b

21 CFR Ch. I (4-1-03 Edition)

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.

(C) *Limitations.* Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) *Cats.* (A) *Amount.* 5 to 10 milligrams per pound of body weight intramuscularly or subcutaneously, once or twice daily.

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

(C) *Limitations.* Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Swine.* (A) *Amount.* 3 milligrams per pound of body weight, intramuscularly, once or twice daily, for up to 3 days.

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

(C) *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.

(b) *Specifications.* Each milliliter contains ampicillin trihydrate equivalent to 150 milligrams of ampicillin.

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

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

(3) *Conditions of use.* *Dogs*—(i) *Amount.* 3 to 5 milligrams of ampicillin per pound of body weight, once a day for up to 4 days.

(ii) *Indications for use.* 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.* Administer intramuscularly. If continued treatment is indicated, oral dosage is recommended. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment are recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37330, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 522.90b Ampicillin trihydrate for sterile suspension.

(a) *Specifications.* When reconstituted, each milliliter contains ampicillin trihydrate equivalent to 50, 100, or 250 milligrams of ampicillin.

(b) *Sponsor.* (1) See 000856 in § 510.600(c) of this chapter for use of 50, 100, and 250 milligrams per milliliter ampicillin suspension.

(2) See 010515 in § 510.600(c) of this chapter for use of 100 and 250 milligrams per milliliter ampicillin suspension.

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

(d) *Conditions of use.* (1) *Dogs*—(i) *Amount.* 3 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Administer by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* 3 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment against strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Administer by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*—(i) *Amount.* 2 to 5 milligrams per pound of body weight once daily by intramuscular injection.

(ii) *Indications for use.* 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.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993; 63 FR 41420, Aug. 4, 1998]

§ 522.90c Ampicillin sodium for aqueous injection.

(a) *Specifications.* When reconstituted, each milliliter contains ampicillin sodium equivalent to 300 milligrams of ampicillin.

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

(c) *Conditions of use. Horses*—(1) *Amount:* 3 milligrams per pound of body weight twice daily.

(2) *Indications for use.* Treatment of respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Escherichia coli*, and *Proteus mirabilis*, and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus*

spp., *E. coli*, and *P. mirabilis*, when caused by susceptible organisms.

(3) *Limitations.* Administer either intravenously or intramuscularly. Treatment should be continued 48 hours after all symptoms have subsided. If no response is seen in 4 to 5 days, reevaluate diagnosis. Not for use in horses or other 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 37331, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995]

§ 522.144 Arsenamide sodium aqueous injection.

(a) *Chemical name.* [[(*p*-Carbamoylphenyl) arsylene]dithio diacetic acid, sodium salt.

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains 10.0 milligrams of arsenamide sodium.

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

(d) *Conditions of use.* (1) For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis*.

(2) It is administered intravenously at 0.1 milliliter per pound of body weight (1.0 milliliter for every 10 pounds) twice a day for 2 days. For dogs in poor condition, particularly those with evidence of reduced liver function, a more conservative dosage schedule of 0.1 milliliter per pound of body weight daily for 15 days is recommended.

(3) Restricted to use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 43 FR 27785, June 27, 1978; 45 FR 56798, Aug. 26, 1980; 55 FR 26683, June 29, 1990]

§ 522.147 Atipamezole hydrochloride.

(a) *Specifications.* Each milliliter of sterile injectable solution contains 5.0 milligrams of atipamezole hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Inject intramuscularly the same volume as that of medetomidine used.