

§ 522.84

Dosage can be repeated every 12 hours, as indicated.¹

(3) Not for use in animals intended for food purposes.¹

(4) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.84 Beta-aminopropionitrile fumarate.

(a) *Specifications.* Each vial contains 7.0 milligrams of beta-aminopropionitrile fumarate sterile lyophilized powder which is reconstituted for injection with 10 milliliters of sterile physiologic saline, USP.

(b) *Sponsor.* See No. 064146 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 7 milligrams (10 milliliters) intralesionally every other day for 5 treatments beginning about 30 days after initial injury.

(ii) *Indications for use.* For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in the adult horse where there is sonographic evidence of fiber tearing.

(iii) *Limitations.* Single dose container for intralesional injection. Do not use in horses with dermal irritation or open skin lesions in the injection area. Do not administer intraarticularly, into the tendon sheath, or in the presence of concurrent limb fractures. Do not use in breeding animals since the effects on fertility, pregnancy, or fetal health have not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44382, Aug. 19, 1998]

§ 522.88 Sterile amoxicillin trihydrate for suspension.

(a)(1) *Specifications.* Each vial contains 3 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 100 or 250 milligrams per milliliter for use as in paragraph (d) of this section.

(2) Each vial contains 25 grams of amoxicillin as the trihydrate. The pow-

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

der is reconstituted with sterile water for injection USP to a concentration of 250 milligrams per milliliter for use as in paragraph (e).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.38 of this chapter.

(d) *Conditions of use in dogs and cats*—(1) *Amount.* 5 milligrams per pound of body weight daily.

(2) *Indications for use*—(i) *Dogs.* 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*; genitourinary 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*; bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; soft tissue infections (abscesses, lacerations, and wounds), due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(ii) *Cats.* Treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* 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*.

(3) *Limitations.* For use in dogs and cats only. Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 hours after the animal has become afebrile or asymptomatic. If no improvement is seen within 5 days, review the diagnosis and change therapy. As with all antibiotics, appropriate in vitro culturing susceptibility testing of samples taken before treatment should be conducted. Federal law restricts this